Pharmacy Provider Manual

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About Us

In an environment where plan sponsors are increasingly looking for greater transparency and accountability, Navitus Health Solutions, LLC (owned by SSM Health and Costco Wholesale Corporation) stands alone as the industry alternative to traditional models with a strong commitment to lowering prescription costs. As such, we offer a powerful solution that is proven to take the unnecessary costs out of pharmacy benefit management. We call it Pharmacy Benefits Reinvented. Using this approach, we have been helping plan sponsors of all types and sizes reduce their costs since our inception in 2003.

From the beginning, we have challenged the status quo. In fact, our founder, Robert Palmer, believed that PBMs needed to evolve to better align with the client's needs. True to those beliefs, today we offer an independent and full disclosure business model to ensure complete alignment with our client's goals. To accomplish this, we value:

- Exceptional Experiences Delivered by Passionate Employees in a Diverse and Inclusive Environment
- 100% Pass Through with Financial & Operational Transparency
- Optimized Health Outcomes at the Lowest Net-Cost
- Outstanding Quality & Compliance
- Flexible, Innovative and Collaborative Solutions
- A Consistent, Connected Technology Experience As a result, we've helped many clients over the years to reinvent their pharmacy benefits and achieve greater savings.

Our Mission: Leading with integrity, we enhance people's lives with a seamlessly connected pharmacy experience that improves health, lowers costs, and eliminates complexity.

100% Pass Through: We pass 100% of all discounts or rebates we receive directly back to our clients. All our revenue is based on a set admin fee.

Lowest Net Cost: While rebates and discounts are important, we focus on all factors to reduce overall cost, including formulary and drug mix.

Clinical Care Model: Our patient-centered model works to improve health outcomes.

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Definitions

340B Laws means all applicable Federal and State Laws, regulations, guidance, and notices relating to the 340B Program, as well as Federal and State anti-kickback and self-referral Laws and State and local pharmacy practice and licensing Laws.

340B Program means the drug-pricing program implemented under Section 340B of the Public Health Services Act[1], as amended and related guidance and notices issued by HRSA and OPA, under which manufacturers that sell Covered Outpatient Drugs to Covered Entities at prices that do not exceed a statutorily determined price.

340B Pharmacy Services means the comprehensive pharmacy services provided to patients.

Agreement means the contractual agreement between Navitus and a Provider, including a chain or pharmacy services administration organization, to provide Covered Products to Members including all addendums, exhibits, and other letters of understanding.

Assisted Living Facility means a system of housing and limited care that is designed for senior citizens who need some assistance with daily activities but do not require care in a nursing home.

Average Wholesale Price (AWP) means the average wholesale price for a given pharmaceutical product in effect in Navitus' systems on the date the prescription was dispensed, as published by Medi-Span or another national drug database reporting service subscribed to by Navitus and updated weekly in Navitus' claims processing system.

Brand Drug means a prescribed drug designated as Brand Drug according to Navitus in its systems and modified from time to time consistent with designations provided to Navitus by its drug database reporting service. Medi-Span Brand Drugs include those medications with a Multi-Source Code of (M), (N), or (O) except where the claim is submitted with a DAW code of "5", in which case it shall be considered a Generic Drug.

[1] 42 USC §256b

Calculated Price means the applicable reimbursement formula with respect to a Prescription Drug that is a Covered Product as set forth in each network addendum, including Part D Drugs, as agreed to by Participating Pharmacy for reimbursement on behalf of Participating Pharmacy Locations in connection with this Agreement.

Clean Claim means a claim, which contains all pertinent information necessary for submission and passes all adjudication edits, in accordance with the standards of the National Council for Prescription Drug Programs (NCPDP). A Clean Claim will have no defect or impropriety, including a lack of required substantiating documentation, or circumstances requiring special treatment that prevents timely payments from being made on the claim.[2]

Clerical error means a discrepancy such as a typographical error by the pharmacy that does not result in financial or other harm to the member or payor.

Coordination of Benefits (COB) and Subrogation means Participating Pharmacy agrees to cooperate with Navitus in the effective implementation of COB and subrogation programs, including, but not limited to, online adjudication for COB claims.

[2] WAC 284-43-321(3)

Compounded Prescription Drug means a Prescription Drug[3], which would require the dispensing pharmacy to produce an extemporaneously produced mixture containing one (1) or more Federal legend drugs. The Compounded Prescription Drug:

- contains ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding
- does not contain a drug product that appears on a list published by the FDA Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective
- the active prescription medication component(s) are in therapeutic amounts, based on scientific literature or national compendia
- the use for which the Compounded Prescription Drug product is being prescribed is supported by FDA approval of the active ingredient(s), or is supported by adequate medical and scientific evidence in the medical literature for that diagnosis and for the method or route of delivery
- are not drug products that are copies of a commercially available drug product.

A prescription will not be considered a Compounded Prescription Drug if it is reconstituted or if, to the active ingredient, only water, alcohol, sodium chloride solutions, or any other diluent, or bulk chemical products are added.

Copayment, Coinsurance or Deductible means the amount of money a Member is required to pay Participating Pharmacy for Covered Products in accordance with that Member's Plan Specifications and the terms of the Agreement.

Cost Sharing Amount means such Copayment, Coinsurance, Deductible, or other Cost Sharing Amount to be paid by a Medicare Member for Part D Drugs in accordance with Medicare Plan Specifications and the Medicare Modernization Act.

Covered Entity means a covered entity as defined under 42 USC §256b(a)(4)(A)-(M) and meeting the requirements under 42 USC §256b(a)(5)(A)-(D).

Covered Outpatient Drugs means the 340B products defined in Section 1927(i) of the Social Security Act (42 USCS §139(r)-8(k)(2)).

[3] 21 U.S.C. § 353a(b) and its implementing regulations

Covered Pharmacy Service(s) means, with respect to Participating Pharmacy, the dispensing of Covered Products, Part D Drugs, and the provision of other related services, which a Member is entitled to receive, and for which the appropriate Payor is obligated to pay, pursuant to applicable Plan Specifications and Agreement.

Days' Supply means the number of days the dispensed quantity of a covered product is expected to last. The Days' Supply is calculated as the quantity dispensed divided by the number of units used each day as directed by the prescribing Practitioner's direction for use and shall be subject to each Payor's Plan Specifications. Participating Pharmacy for purposes of calculation of Copayment, Coinsurance or Deductible must submit via On-Line Adjudication Processing the accurate number of Days' Supply of a covered product dispensed to Member.

Dispensing Fee means the amount, if applicable, to be funded by the appropriate Payor and remitted by Navitus to Participating Pharmacy for dispensing each covered product to a Member, which may be a part of the Calculated Price as set forth in each applicable network addendum.

Drug Enforcement Administration (DEA) means a Federal Law enforcement agency, under the United States Department of Justice, tasked with combating drug smuggling and use within the United States.

Drug Utilization Review (DUR) means a review of drugs used in a population to determine effectiveness, potential dangers, problems with drug interaction, cost savings and other issues.

Employee Retirement Income Security Act (ERISA) is a Federal Law that sets minimum standards for most voluntarily established pension and health plans in private industry to provide protection for individuals in these plans.

Exclusion Lists means those lists administered by the Office of Inspector General (OIG) and the General Services Administration (GSA), which includes the System for Awards Management (SAM) list and any State-specific exclusion lists. This also includes exclusion lists administered by State healthcare programs including but not limited to Medicaid. The lists provide information to the health care industry, patients and the public regarding individuals and entities currently excluded from participation in Medicare, Medicaid and all other Federal health care programs.

Force Majeure A party shall not be deemed to have breached this Agreement if its delay or failure to perform all or any part of its obligations hereunder results from a condition beyond its reasonable control, including without limitation, acts of God or the public enemy, flood or storm, strikes, riots, terrorist acts, war or other outbreak of hostilities, natural disaster, power or communication line failure, statute, or rule or action of any Federal, State or local government agency.

Formulary means a list of preferred Prescription Drug developed, published, and periodically revised by Navitus' pharmacy and therapeutics committee or a Payor, which Practitioners are encouraged to prescribe, and Participating Pharmacies are required to dispense, consistent with their professional judgment and applicable Law, and which Members are encouraged to use.

Fraud, Waste and Abuse (FWA) means[4]:

Fraud: an intentional act of deception, misrepresentation, or concealment in order to gain something of value.

Waste: over-utilization of services (not caused by criminally negligent actions) and the misuse of resources.

Abuse: excessive or improper use of services or actions that is inconsistent with acceptable business or medical practice. Refers to incidents that, although not fraudulent, may directly or indirectly cause financial loss.

General Services Administration (GSA) administers System for Award Management (SAM), which contains debarment actions taken by various Federal agencies, including exclusion actions taken by the OIG. You may access SAM at SAM.gov | Data Services.

Generic Drug means a prescribed drug designated as Generic Drug according to Navitus in its systems and modified from time to time consistent with designations provided to Navitus by its drug database reporting service and/or a multi-source drug as defined by a drug data base compendia vender such as Medi-Span that assigns values to drugs labeling them as Generic Drugs that are identical, or bioequivalent to a Brand Drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Medi-Span Generic Drugs include those medications with a Multi-Source Code of (Y). Claims submitted with a Multi-Source Code, as defined by Medi-Span, of "O" and also submitted with a DAW code of "5" shall also be considered a Generic Drug.

[4] 42 CFR Section 423.504(b)(vi) and 422.503 (b)(4)(vi)

HHS means the United States Department of Health and Human Services.

HIPAA means the Health Insurance Portability and Accountability Act of 1996 as amended and successor rules as amended that apply privacy, security and standard transaction rules and regulations[5,6,7] to protected health information (PHI).

HIPAA Compliance means the parties agree to execute such other Documents or amendments hereto and take such other actions as may be necessary to comply with applicable Law, including, but not limited to, the HIPAA Rules.

HIPAA Rules mean the medical records privacy, security and standard transaction rules and regulations[8,9,10]

Home Infusion means the administration of covered Part D Drugs using intravenous, subcutaneous, and epidural routes (into the bloodstream, under the skin or into the membranes surrounding the spinal cord).

HRSA means the Health Resources and Services Administration of HHS.

Law means any Federal, State, or local Law, ordinance, rule, regulations or judicial or administrative interpretation thereof.

LTC Facility or LTC Facilities means a skilled nursing facility as defined in Section 1819(a) of the Social Security Act or a medical institution or nursing facility for which payment is made for an institutionalized individual.[11] "LTC Facility" does not include an assisted living facility, an independent living facility, a congregate care retirement community, an inpatient hospice, a group home, or other residential setting for the care of the elderly or disabled, which in each case manages the distribution of medications to its residents using a unit dose or other specialized medication packaging and administration system. An LTC Facility is a facility with an NCPDP Patient Residence Code of 03 or 09.[12]

[5] 45 CFR Parts 160, 162 and 164 and successor guidance and regulations
[6] Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of the American Recovery and Reinvestment Act of 2009
[7] HIPAA Omnibus Rule of 2013
[8] 45 CFR Parts 160, 162 and 164 and successor guidance and regulations
[9] Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of the American Recovery and Reinvestment Act of 2009
[10] HIPAA Omnibus Rule of 2013
[11] Section 1902(q)(1)(B) of the Social Security Act
[12] NCPDP field 384-4X

Managed Care Organization (MCO) means a company subject to State insurance Laws, which uses a method of health care delivery that focuses on collaboration among and coordination of all services to avoid overlap, duplication, and delays and to reduce costs. These companies agree to provide most Medicaid benefits to people in exchange for a monthly payment from the State.

Maximum Allowable Cost (MAC) means the compensation level established and modified by Navitus in its discretion from time to time.

Medicare Modernization Act means the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[13] codified in Sections 1860D-1 through 1860D-41 of the Social Security Act, and its implementing regulations.

Members means individuals, including Medicare Members, covered under a Payor's plan.

National Council for Prescription Drug Programs (NCPDP) means the national council for prescription programs or its successor.

National Drug Code (NDC) means a unique 10 or 11-digit, 3-segment numeric identifier assigned to each medication.[14]

Network Pharmacy(ies) means the pharmacies that have entered into Participating Pharmacy Agreements with Navitus to provide Covered Pharmacy Services to Members.

National Plan & Provider Enumeration System (NPPES) means the National Plan and Provider Enumeration System assigns the unique health care provider and health plan identifier.

National Provider Identifier (NPI) means the National Provider Identifier provided by the Centers for Medicare and Medicaid Services through the National Plan & Provider Enumeration System (NPPES), or its successor, as published by NCPDP or another NPI reporting service used by Navitus.

Office of Inspector General (OIG) means the Federal government entity dedicated to combating fraud, waste, and abuse and to improving the efficiency of Health and Human Service (HHS) programs. This entity is also responsible for administrating the List of Excluded Individuals/Entities (LEIE).

[13] Sections 1860D-1 through 1860D-41 of the Social Security Act, and its implementing regulations
[14] Section 510 of the US Federal Food, Drug and Cosmetic Act

Online Adjudication Processing means the transmission of Prescription Drug claims from Participating Pharmacy to Navitus in compliance with the current transaction standards as of the date of service set forth in applicable Law including the HIPAA Rules and, in turn, Participating Pharmacy receiving, via online messaging, information including, but not limited to, eligibility and coverage determination, and applicable Deductibles, Coinsurance and Copayments.

OPA means the Office of Pharmacy Affairs of HHS.

Overpayment means the amount of money received for Covered Pharmacy Services by a Participating Pharmacy in excess of the Calculated Price less applicable Coinsurance, Copayment, Deductible, or the amount of money paid for on behalf of an individual determined to be not a Member on the date of service or for non-Covered Pharmacy Services. For purpose of clarification, any determination that a Member was not eligible to receive benefits under the applicable Plan, even if such determination is made after the date of On-Line Adjudication, may result in a payment being deemed an Overpayment.

Payor means an employer, government or governmental authority, health maintenance organization, insurance company, managed care organization, preferred provider organization, self-funded plan, or group, third party administrator or any other entity or individual responsible for funding payments of Covered Pharmacy Services and has selected one or more of Navitus' networks.

Pharmacy Care Incentive Program (PCI) means one or more reimbursement incentives to a Pharmacy for cognitive services provided to Members.

Plan Specification means the coverages, exclusions, and limitations of Covered Products under a Payor's health benefit plan, as may be identified through an On-Line Adjudication Processing of Covered Products; excluded items; applicable Coinsurance, Copayment and Deductible amounts; benefit maximums; and other items in connection with a particular Plan Specification required by a Payor.

Part D Plan Sponsor means a nongovernmental entity that is certified as meeting the requirements and standards that apply to entities that offer Medicare Part D plans.[15]

[15] 42 CFR 417.472, 42 CFR Part 423 or 42 CFR Part 422

Part D Plan means Prescription Drug coverage that is offered under a policy, contract, or plan that has been approved[16] and that is offered by a PDP sponsor that has a contract with the Centers for Medicare and Medicaid Services that meets the contract requirements.[17]

Practitioner means a physician or other health provider licensed in the state where the prescription is issued and who is authorized by Law to prescribe medication, devices and/or supplies to individuals, including Medicare Members.

Preclusion means a pharmacy or provider who is not enrolled with Medicare or who has been removed from Medicare participation due to enrollment violations

Preferred Drug List (PDL) means a list of preferred drugs comprised of various therapeutic classes.

Prescription Drugs means Federal legend drugs requiring a prescription and all Compounded Prescription Drugs pursuant to federal and/or state Law. Bulk chemicals, medical food supplements, and nutritional additives not approved for dispensing by prescription are not considered federal legend drugs.

Prescription Drug Pricing Standard means any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts that are based upon Average Wholesale Price, Wholesale Acquisition Cost, average manufacturer price, average sales price, Maximum Allowable Cost, or other cost, whether publicly available or not.

Protected Health Information (PHI) means individually identifiable health information related to the past, present, or future physical or mental health or condition of a Member; the provision of health care to a Member; or the past, present or future payment for the provision of health care to a Member, as more fully defined in the HIPAA Rules or otherwise deemed confidential under federal or state Law.

Participating Provider/Pharmacy means an entity licensed to dispense Covered Pharmacy Services and contracted with Navitus Health Solutions to provide Covered Pharmacy Services.

Risk Evaluations and Mitigation Strategy (REMS) means a strategy to manage a known or potential serious risk associated with a drug or biological product.

[16] 42 CFR 423.272, 42 CFR 422.502 or 42 CFR 417.472

[17] Subpart K of 42 CFR Part 423 or subpart K of 42 CFR Part 422

Skilled Nursing Facility means a health-care institution that meets Federal criteria for Medicaid and Medicare reimbursement for nursing care including especially the supervision of the care of every patient by a Practitioner, the employment full-time of at least one registered nurse, the maintenance of records concerning the care and condition of every patient, the availability of nursing care 24 hours a day, the presence of facilities for storing and dispensing drugs, the implementation of a utilization review plan, and overall financial planning including an annual operating budget and a 3-year capital expenditures program.

Unbreakable package, *also referred to as a unit-of-use package,* means a prescription medication that contains a quantity designed and intended to be dispensed directly to a Member without modification except for the addition of a pharmacy prescription label.

Usual and Customary Price means the retail price charged by the dispensing Participating Pharmacy Location for a particular Prescription Drug in a cash or uninsured transaction, on the date such Prescription Drug is dispensed by such Participating Pharmacy Location exclusive of sales tax, but including any discounts provided for prescription drug savings card or other similar discounts claimed.

Wholesale Acquisition Cost (WAC) means the Wholesale Acquisition Cost for a given pharmaceutical product in effect in Navitus' systems on the date the prescription was dispensed, as published by Medi-Span or another national drug database reporting service subscribed to by Navitus and updated weekly in Navitus' claims processing system.

Navitus Contact Information

Pharmacy Help Desk:

Assists Participating Pharmacies with claim processing for Navitus members across all lines of business Available 24 hours a day, 7 days a week, 365 days a year

Commercial Pharmacy Help Desk.....844-268-9789
(or the toll-free number on the back of the pharmacy benefit card)

Discount Card Help Desk (Mon.-Fri., 8:30 a.m.–5:00 p.m., CST).....866-809-9382
Website: www.navitus.com

Medicaid Help Desk (refer to each state section for details)
Website: www.navitus.com

Medicare Part D Pharmacy Help Desk.....866-270-3877
Website: www.medicarerx.navitus.com

Pharmacy Provider Services:

Available to assist with credentialing, contracts, reimbursement, network set-up, MAC and pricing research (8:00 a.m.–5:00 p.m., M-F, CST)

Contracting.....608-298-5775
Email: providerrelations@navitus.com Fax.....608-298-5875

Credentialing.....608-298-5776
Email: credentials@navitus.com Fax.....608-298-5876

Payment.....608-298-5777
Email: remittanceinquiry@navitus.com Fax.....608-298-5877

Pricing Research.....608-298-5778
Email: pricingresearch@navitus.com Fax.....608-298-5878

Prior Authorizations:

Commercial www.navitus.com.....866-333-2757
(or the toll-free number on the back of the Member's pharmacy benefit card)
Medicare Part D www.medicarerx.navitus.com.....866-270-3877
Medicaid (please refer to each state section for details)

Audit Department:
Direct Line (Appleton).....920-221-4100
Fax.....866-595-0357 or 920-221-4600
Email: Auditing@Navitus.com
Report Fraud, Waste and Abuse
Dial Anonymous Hotline.....855-673-6503
Email: SIU@navitus.com

Navitus Communications
Navitus strives to ensure its Participating Pharmacies are informed of information that may affect their businesses. Below are various methods of communication we use:

- **Bulletins/Fax Blasts:** We use this form of communication when there is a unique issue or area of concern for which pharmacies need to be aware. This information may be sent comprehensively to all pharmacies or to the affected localized area.
- **Emails/Telephonic:** Our exceptional Customer Service Department is available to pharmacies, pharmacists, and corporate offices. We are available for direct, personalized support via telephone or email, whichever is most convenient for the pharmacy.
- **Newsletter:** Our priority is to ensure participating pharmacies are kept informed on current and prospective circumstances. All Participating Pharmacies have access to our quarterly Pharmacy Newsletter. The newsletter is provided via fax or email and is available on our website.
- **Payor Sheet:** Payor sheets are available on our website, making it easy to accurately process claims.
- **Pharmacy Provider Manual:** Navitus' Pharmacy Provider Manual is located on our website. The manual enables pharmacies to process claims correctly and guides pharmacies on how to obtain authorizations, request pricing research, respond to audits, etc.
- **Point-of-Sale (POS) Messaging:** We employ a POS system that prospectively informs the pharmacy of issues concerning the claim.
- **Website** (www.navitus.com): The Navitus website is accessible 24/7and includes the latest bulletins and newsletters, along with a wealth of information to aid pharmacies. The website is a valuable resource for participating pharmacies that includes the most up-to-date policies and procedures, guidance, formulary, and forms necessary to provide Covered Pharmacy Services to Members.

All information and materials provided by Navitus (including without limitation, contracts, fee schedules, policies and procedures, and any pharmacy procedures manual) shall remain the sole and exclusive property of Navitus. The Participating Pharmacy shall not disclose or permit the disclosure of any or such information or materials or use them except as provided in this Agreement. This provision shall survive the expiration or termination of this Agreement for any reason whatsoever.

Client Contact Information

Costco Health Solutions	877-908-6024
L.A. Care CalMediConnect	844-268-9785
L.A. Care Commercial, Health Kids, PASC	844-268-9787
L.A. Care Exchange	844-268-9784
Texas Medicaid/CHIP Help Desk (24/7)	800-252-8263
North Carolina Medicaid	888-245-0179
Alliance Health Pharmacy Service Line	855-759-9300
Alliance Health Member and Recipient Service Line	800-510-9132
Alliance Health Prior Authorization	855-759-9300
Vaya Health Pharmacy Service Line	1-800-540-6083
Vaya Health Member and Recipient Service Line	1-800-962-9003
Vaya Health Prior Authorization	1-800-540-6083

Rights And Responsibilities

Navitus' Customer Care Responsibilities

The cornerstone of Navitus' Customer Care is consistent and high-touch service, well-trained and knowledgeable staff, and timely responses. We strive to resolve each call correctly, completely, and professionally during one call. The first time. Our relentless pursuit of superior customer service is what sets us apart from the competition.

Care Commitment to Participating Pharmacies—We will:

- be **responsive** to the pharmacy's needs
- be **respectful** of our pharmacies at all times
- be **realistic** about what we can or cannot do
- **resolve** each pharmacy issue in a timely manner
- take **responsibility** for our pharmacy relationships

Navitus devotes multi-disciplinary teams of individuals who are available to assist Participating Pharmacies with the coordination of day-to-day functions. See contact information.

Confidentiality and Proprietary Rights

Member information related to Covered Pharmacy Services and other records that identify a Member shall be treated by the Participating Pharmacy as confidential and proprietary. All materials that relate to Navitus' pricing, contracts, programs, services, business practices and procedures are proprietary and confidential. The Participating Pharmacy must maintain the confidential nature of such materials and return them to Navitus upon termination of the Agreement.

Pharmacy Rights

- To be treated with respect and dignity
- To receive prompt and courteous responses to inquiries
- To receive timely communications from Navitus regarding information that affects pharmacy services
- To expect timely reimbursement for covered drug products and services
- To express a complaint and receive a response within a reasonable amount of time
- To expect confidentiality regarding business and credentialing documents
- A dispensing pharmacist is under no obligation to dispense a prescription, which, in his/her professional opinion, should not be dispensed

Pharmacy Responsibilities

Compliance

- Comply with the Laws and provide services compliant with the highest standards
- Pharmacies offering digital information, ordering, or contact via websites, documents, and apps should ensure those services are accessible to people regardless of disability by conformance to Web Accessibility Content Guidelines (WCAG) 2.1 AA. Digital widgets and/or overlay products are not an acceptable alternative to native conformance. Comply with all Laws regarding the confidentiality, privacy, security and disclosure of medical records or other health and enrollment information, including, but not limited to the HIPAA Rules; (b) with respect to a Member's information, maintain procedures that specify how and why information is used within the organization and to whom and for what purposes information is disclosed outside the organization; (c) ensure that medical information is released in accordance with applicable Law, including but not limited to, court orders and subpoenas; (d) maintain such records and information in an accurate and timely manner; and (e) ensure timely access by Members to the records and information that pertain to them[18,19]
- Comply with the policies and procedures of the Payors, their Plan Specifications and those rules and regulations published by Navitus from time-to-time in publications such as, but not limited to, Navitus' Pharmacy Provider Manual, Navitus' Pharmacy Bulletins, Navitus' Pharmacy Newsletter and Navitus' website, Pharmacy Portal - Home (navitus.com).
- Maintain and enforce comprehensive policies and procedures for operation
- Treat Navitus Documents that relate to pricing, contracts, programs, services, and business practices as proprietary and confidential
- Monitor your state PDMP program (if applicable) as part of your FWA process to limit improper claims associated with member or prescriber behaviors evident in the PDMP.

Filling/Dispensing Prescriptions

- Fill prescriptions per the Practitioner's directions
- Coordinate with the prescribing Practitioner
- Assure the authenticity of the Prescription Drug order
- Seek to prevent Prescription Drug orders from being filled by multiple pharmacies
- Ensure reasonable verification of the identity of the Member, Practitioner, and, if appropriate, caregiver including member's personal representative
- Verify with appropriate facility the patient's residence and bill applicable Patient Residence Code (PRC)
- Ensure Members receive all medications for which they are eligible
- Coordinate benefits when a Member also receives Medicare Part D services or other insurance benefits

[18] HIPAA Privacy Guidance - https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/index.html
[19] HIPAA Security Guidance - https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html?language=es

- Inform Members or caregivers about drug recalls
- Provide instructions to the Member regarding storage, dosing, side effects, potential interactions, and use of the medication dispensed in accordance with professional practice guidelines
- Collect from the Member the amount, which is lesser of the applicable Coinsurance, Copayment, Deductible Usual and Customary Price or Calculated Price
- In the event the Usual and Customary Price and the Calculated Price are both less than the applicable Coinsurance, Copayment or Deductible, Participating Pharmacy shall accept the lesser of the Usual and Customary Price or the Calculated Price as payment-in-full for such Covered Product claim
- Maintain the pharmacy Location and equipment in first-class condition
- Submit claims electronically, at the point of sale, only for the Member for whom the Practitioner wrote the prescription
- Maintain prescription error prevention measures and maintain an incident record of all actual and potential injuries as a result of dispensing errors
- Assure that medications and devices are maintained within appropriate temperature, light and humidity standards during storage and shipment
- Utilize accurate NPI numbers that correctly correspond to the Participating Pharmacy and Practitioner in the correct NCPDP data fields

Medications/Contra-Indications

- Conduct prospective drug utilization review at point of sale
- Dispense preferred Formulary products for non-preferred products wherever possible and adhere to the Formulary and Preferred Drug List (PDL)
- Pharmacies should adhere to State-specific Laws for Generic substitution
  Display all DUR alerts to the dispensing pharmacist and respond to all online edits and assure, per OBRA 1990 Law, that prescriptions for covered outpatient drugs are appropriate, medically necessary, and not likely to result in adverse medical results
- Take appropriate action and report suspected adverse drug reactions and errors

Member Service

- Provide Members the same quality pharmacy services, including, but not limited to, consultative services as required by Law, as it provides Participating Pharmacy's other customers
- Ensure Members receive equal treatment, access, and rights without regard to race, color, gender, religion, national origin, or any other basis forbidden by Law. Participating Pharmacies shall make available or arrange language assistance (i.e., interpreters and/or language-appropriate written materials) to Members with limited English proficiency (LEP)
- Participating Pharmacies must be compliant with applicable access standards related to the Americans with Disabilities Act of 1990 (or its successor)

- Educate Members and caregivers about the appropriate means to dispose of expired, damaged and unstable medications

Participating Pharmacies are Prohibited from:

- Serving as an appointed representative of a member for purposes of grievance or appeals related to non-covered drugs or prior authorization denials. Participating Pharmacies and pharmacists may submit information in support of a grievance or appeal. However, direct submission or appeal by the Participating Pharmacy may be a conflict of interest or create an inappropriate relationship between the pharmacy and member
- Using waivers, discounts, reductions, or increases to Cost-sharing
- Billing, charging, collecting a deposit from, seeking compensation, remuneration, or reimbursement from, or having any recourse against, a Member or other persons acting on their behalf other than Payor, for services provided pursuant to the Agreement
    - This provision shall not prohibit collection of Deductibles, Copayments, Coinsurance, and/or non-covered services, which have not otherwise been paid by a primary or secondary carrier in accordance with regulatory standards for coordination of benefits, from Members in accordance with the terms of the Member's Plan Specifications[20]
- Collection from the Member for sums owed by Navitus or Payor. Participating Pharmacy and its agents, trustees, or assignees may not maintain any action against a Member to collect sums owed by Navitus and/or Payor[21] during the term and following any contract termination[22]
- Billing the Member for covered services (except for Deductibles, Copayments, or Coinsurance) where payment is denied because Participating Pharmacy has failed to comply with the terms or conditions of the Contract or this manual[23]
- Refusing to provide services to Members due to reimbursement dispute or any other financial concern as set forth in addenda or amendments to this Agreement
- Charging the Member costs above Usual and Customary or retail pricing
- Charging in excess of what Navitus returns in the claim response

[20] WAC 284-43-320(2)(a)
[21] RCW 48.44.202(4)(a) and (b); RCW 48.46.243(4).
[22] WAC 284-43-320(2)(e).
[23] WAC 284-43-320(2)(d)

Maintenance of Records

Pharmacy must obtain and maintain accurate, complete, up-to-date, and otherwise in conformance with generally accepted standards and good pharmacy practice, all Documents and records related to the provision of Prescription Drug Benefits to Members. Such Documents[24] and records include, but are not limited to:

- Original prescriptions
- Signature and/or electronic tracking logs
- Daily prescription logs
- Wholesaler, manufacturer, and distributor invoices
- Refill information
- Prescriber information
- Patient profiles/doctor orders

Participating Pharmacy agrees in accordance with applicable Law, Navitus, its Payors, HHS[25], State Authorities, the Comptroller General and/or any of their designees shall have the right to inspect, evaluate and audit any and all Documents: (a) related to the contract between CMS and any Payor; (b) related to the services performed or determination of amounts payable under these terms; (c) as the Secretary of HHS, any Payor or Navitus may deem necessary to enforce these terms; (d) related to quality of care or investigating the grievances or complaints of Members[26]; and (e) related to the performance of these terms and services performed on behalf of a Medicare Member.

Participating Pharmacy agrees to maintain all such Documents related to the services contemplated by these terms for a period of not less than ten (10) years from the expiration or termination of these terms[27] or from the completion of any audit contemplated by these terms or as required by Law, whichever is later unless: (i) CMS or Navitus determines there is a special need to retain a particular Document or group of Documents for a longer period and notifies Participating Pharmacy before the normal disposition date of such Documents; (ii) there is a termination, dispute or allegation of fraud or similar fault, in which case the retention may be extended by CMS or Navitus to six (6) years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or (iii) CMS or Navitus determines that there is a reasonable possibility of fraud or similar fault, in which case CMS or Navitus may inspect, evaluate and audit Participating Pharmacy. Participating Pharmacy is required to maintain prescription records in their original format for the greater of three (3) years or the period required by State Laws and allow those records to be transferred to an electronic format that replicates the original prescription for the remaining seven (7) years of the ten (10) year record retention requirement.

[24] WAC 284-43-320(6)
[25] 42 CFR §423.505(i)
[26] WAC 284-43-320(6)
[27] 42 CFR § 423.505(d)

Navitus Provider Requirements

Requirements may vary based on state or payor; please see state-specific sections for additional details.

Participating Pharmacy Qualifications

Participating Pharmacy represents and warrants that Participating Pharmacy and each of its Locations: (a) has the capability to provide the Covered Pharmacy Services to Members in a timely and efficient manner; and (b) satisfies and complies with and shall continue to satisfy and comply with all provisions of these terms.

Participating Pharmacy further represents and warrants as follows: (a) each Location is and shall be able to transmit claims by real time, point-of-sale, On-Line Adjudication Processing and receive from Navitus communications via such On-Line Adjudication Processing; (b) Participating Pharmacy and each Location do and shall possess adequate, appropriate and necessary computer (including all hardware and software), intranet, internet, telecommunications, voice, information, data, database and technology systems, trained and licensed personnel and operational processes, procedures and protocols to participate in Navitus' respective Plan networks on behalf of Payors and to furnish Covered Pharmacy Services to Members in an orderly, efficient, professional and competent manner; (c) Each Location is and shall be capable of processing all electronic or other transactions as a result of Covered Pharmacy Services in compliance with all applicable Laws and Medicare program requirements.[28]

Navitus deems retail participating pharmacies as pharmacies servicing in a local area. Requirements may vary based on state or payor; please see state-specific sections for additional details.

Navitus does not recognize a place of consignment or other remote inventory arrangement at a non-pharmacy outpatient location from which medication or supplies of the Participating Pharmacy are dispensed and billed as a "Location" of the Participating Pharmacy. Examples include physician offices or outpatient clinics. This does not comply with the Participating Pharmacy Agreement, or the Pharmacy Responsibilities listed in this Manual.

Pharmacies may allow for pharmacists to virtually verify product for accuracy and approve for dispensing. Virtual verification processes must be documented in the pharmacy's policy and procedures. Pharmacies should ensure that this will not compromise quality of care to the Members.

[28] 42 CFR §423.505(j) and §423.505(b)(17)

Contracting

To become a provider for Navitus, pharmacies, PSAOs and chains must complete and submit a Participating Pharmacy Agreement and applicable amendments for providing pharmacy services. Providers must also submit copies of required documentation to confirm they meet Navitus' credentialing requirements. Notwithstanding any other provision of the Agreement, nothing in the Contract shall be construed to modify the rights and benefits contained in the Member's Plan Specifications. [29]

To obtain a contract from Navitus' Provider Networks:

- Phone 608-298-5775
- Fax 608-298-5875
- Email providerrelations@navitus.com

Documentation Required:

- completed, dated, and signed contract, addendum(s), exhibits and attestations
- photocopy of current, valid and in good standing, State Pharmacy License
- photocopy of current, valid and in good standing, Pharmacist-In-Charge, State Pharmacy License
- photocopy of current, valid and in good standing, DEA certificate
- photocopy of current, general, and professional liability insurance certificate (not less than $1,000,000 per occurrence and $3,000,000 in aggregate or as otherwise required by Law) which will be maintained as Pharmacy's sole cost and expense
- photograph of the dispensing area and store front of the pharmacy

Documentation must be legible.

Submission:

- Mail Navitus Health Solutions; Attn: Pharmacy Network Dept.
  361 Integrity Drive
  Madison, WI 53717
- Email providerrelations@navitus.com
- Fax 608-298-5875

If additional information is needed or if information is incomplete, Navitus will contact the Pharmacy.

[29] WAC 284-43-320(2)(c)

Term and Termination

In the event one or more Locations discontinue participation in its entirety or discontinues participation in the pharmacy networks of one or more Payors' Plans (including, but not limited to, Medicare requirements[30] or those specific instances identified in these terms that permit a Location's suspension, revocation or termination by Navitus or a Payor), then Navitus, on behalf of itself or a Payor, shall have the right to require that the removal of the applicable Locations not allow or cause a termination of the pharmacy's Agreements with Navitus.

Updating Pharmacy Information

Monthly Pharmacy updates are processed utilizing NCPDP information. Please submit changes to NCPDP in a timely manner to ensure timely processing. All changes must be made prior to the NCPDP cutoff date to avoid Member disruption.

NOTE: Be sure any changes being made to NCPDP are also being made with NPPES.

[30] 42 CFR §423.505(i)(4)(ii)

Credentialing/Re-credentialing

Credentialing and re-credentialing initiatives exist to ensure that Participating Providers abide by the criteria established by Navitus, as well as governmental regulations and standards. The applicant must comply with the credentialing and re-credentialing initiatives required by Navitus and agree to provide documentation and other relevant information that may be required in association with such initiatives. Navitus retains the absolute right to conduct a facility review any time a deficiency or breach of standard of care is suspected. If Participating Pharmacy itself becomes excluded, debarred, or ineligible or if Participating Pharmacy has not taken the actions required of it in this section, then Navitus shall have the right, at any time, to terminate the applicable Participating Pharmacy Agreement immediately upon written notice to Participating Pharmacy or take such other corrective or remedial action as warranted under the circumstances. Participating Pharmacies are subject to termination if they fail to return updated credentials in a timely manner.

Please note, requirements may vary based on state or payor; please see state-specific sections for additional details.

Navitus' Credentialing Requirements

Credentialing/Licensing/FWA

- Upon notice by Navitus, return valid, updated credential documentation within the time specified in the notice
- Comply with the standards for pharmacy practice as established by Law for its Locations
- Keep and maintain, in good standing, all valid Federal, State and local Licenses and permits, as required by the Law, to operate a pharmacy
- Maintain its eligibility and the eligibility of its Locations and pharmacists to participate in all Medicare and Medicaid programs, all State pharmaceutical assistance programs and all government-funded health programs where its pharmacies are Located
- Ensure pharmacy Locations and pharmacy staff are duly licensed and permitted to practice pharmacy in each State or jurisdiction where it provides pharmacy services to Members
- Ensure all employees are qualified to perform their professional duties and act within their scopes of licensure
- Be represented by an annually signed FWA attestation regarding ongoing FWA compliance
- Locations marked as non-pharmacy dispensing sites must complete an attestation and submit required documentation to be considered for network participation

Discipline/Exclusion/Sanction:

- Verify that provider and all owners and personnel employed by or contracted by the provider are not on the Exclusion Lists upon new hire/contract and monthly thereafter, unless Laws indicate otherwise

- Immediately remove any person on the Exclusion Lists who is debarred, excluded or ineligible from providing services related to all health care programs or convicted of a criminal felony, take corrective actions
- Inform Navitus immediately that an employee, owner or pharmacy is on any Exclusion List
- Notify Navitus promptly and in writing of all investigations conducted by any State board of pharmacy or other Federal or State authority in connection with the practice of pharmacy and all pending and final disciplinary actions by any such board or authority against Participating Pharmacy or any of its pharmacists

Notification of Changes:

- Notify Navitus, in writing, within one business week of changes in documentation and other information provided to Navitus in connection with credentialing or re-credentialing initiatives
- Notify Navitus within five (5) days of any status change in pharmacy or pharmacist License
- Notify NCPDP and NPPES (as applicable) of changes that pertain to demographics, the opening or closing of a pharmacy, and Location changes, in a timely manner
- Provide notification of changes in legal status or ownership not less than thirty (30) days prior to the effective change date including, but not limited to, i) changes in the fiscal agent or authorized or delegated officials; ii) ownership transfer or acquisition with a controlling interest of greater than 5%; and iii) changes in holding or parent corporation names, Locations, agents, or owners.
- Switching PSAOs 2 or more times within a one-year period will be used during credentialing review and can be used in consideration for network removal.

ATTESTATIONS can be obtained from NCPDP, on the Navitus Pharmacy portal, by contacting Navitus' Credentialing Team at 608-298-5776, or emailing to credentials@navitus.com.

Best Practice: Participating Pharmacies should have a quality assurance policy to aid in reviewing error prevention, analyzing causes, and contributing factors that may lead to medication, system and/or processing errors.

Navitus will perform random audits (no less than annually) of chains' and PSAOs' credentials by requesting the electronic credentialing documentation. Navitus will verify the following during the audit:

- State licensure has been verified in the last year
- DEA certification has been verified in the last year
- General and Professional liability has been verified within the last year
    - Including validation that the chain indicated its License number and company on its store listing

Pharmacy Services Administration Organizations (PSAO)

Participating Pharmacies may delegate contracting responsibilities to a PSAO. Pharmacies are to report their affiliation with a PSAO to Navitus.

PSAOs are required to sign an attestation stating the PSAO on behalf of the affiliated pharmacies,

- have a contractual relationship with their affiliated pharmacies
- are responsible for ensuring their affiliated pharmacies are maintaining valid State Licenses, DEA certification, and general and professional liability insurance coverage
- are responsible for reporting sanctions or investigations that involve the PSAO or its affiliated pharmacies
- are responsible for submitting an attestation regarding their ongoing FWA policies and procedures, ensuring that their affiliated pharmacies continue to meet Navitus' credentialing and compliance standards and follow Navitus' Pharmacy Provider Manual
- are responsible for notifying Navitus of any deficiencies

PSAOs must,

- submit their policies and procedures practices to maintain their pharmacy credentials
- submit a spreadsheet with their affiliated pharmacies listed and include the PSAOs:
    - Pharmacy DEA number and expiration date
    - State License number and expiration date
    - General and Professional liability insurance name, policy number and expiration date
    - Pharmacist-In-Charge License and expiration date

Chains

Chains are required to sign an attestation stating they and their pharmacy Locations,

- are responsible for maintaining valid State Licenses, DEA certifications, and general and professional liability insurance coverages
- are responsible for sanctions or investigations that involve their pharmacy Locations
- are responsible for submitting an attestation regarding their ongoing FWA policies and procedures, ensuring that their pharmacies continue to meet Navitus' credentialing and compliance standards, and follow Navitus' Pharmacy Provider Manual
- are responsible for notifying Navitus of any deficiencies

Chains must submit,

- their policies and procedures practices to maintain their pharmacy credentials
- annually a spreadsheet with their Locations listed and include:
    - Pharmacy DEA numbers and expiration dates
    - State License numbers and expiration dates
    - Liability insurance names, policy numbers and expiration dates
    - Pharmacist-In-Charge Licenses and expiration dates
    - days and hours of operation

Re-Credentialing Standards

Participating Pharmacies are subject to re-credentialing at a minimum of every three years. The process for re-credentialing is identical to that of credentialing, except that Navitus will also consider the following:

- Member complaints
- Quality improvement review studies
- Utilization management review studies
- Pharmacy audits
- Repeated non-response or delayed response to compliance related documents
    - Corrective action requests, FWA attestation, Off-Shore attestation, etc.
- Customer satisfaction surveys
- Review of state license actions of pharmacy and of employed pharmacy personnel
- Review of claims activities over preceding two years

Navitus' Credentialing Committee

The Navitus Credentialing Committee reviews providers that do not meet the Navitus network criteria, contain deficiencies identified via the credentialing process or have issues with the integrity of administrative policies and procedures. The Credentialing Committee will determine the type and extent of the occurrence and make a determination with regard to participation status or the need for further review and recommendations. Occurrences and corrective actions are placed in the provider's credential file, as appropriate. Navitus will notify the provider, in writing, of any recommendation to deny, suspend, or terminate participation in the Navitus Network. The provider is also informed of its right to appeal the decision, in writing, to Navitus Provider Relations within thirty business days of the receipt of the decision.

Court Orders, Subpoenas or Governmental Requests

If Navitus receives a court order, subpoena or governmental request relating to a Participating Pharmacy, Navitus will comply with such order, subpoena or request and the Participating Pharmacy must indemnify and hold harmless Navitus for, from and against any and all costs (including reasonable attorney's fees and costs), losses, damages or other expenses Navitus may incur in connection with responding to such an order, subpoena or request.

Fraud, Waste and Abuse and Compliance

Compliance and Fraud Program and Complaints

Participating Pharmacy agrees to cooperate with Navitus, authorities, and applicable delegates in connection with the investigations and grievance procedures involving fraud, complaints, or other rules established pursuant to and made available by each Plan to Members including Medicare.[31]

- Participating Pharmacy agrees to cooperate in connection with any investigation of suspected or actual non-compliance and program by Navitus or its Payors to support compliance, resolve issues with HIPAA Rules, or protect against fraud, waste, and abuse. [32]
- Participating Pharmacy agrees to promptly notify Navitus of any suspected or actual fraud or compliance issue pertaining to services under this Agreement.
- Participating Pharmacy agrees to promptly notify Navitus of a breach or security incident as defined under the HIPAA Rules and inform Navitus of impacted Members where such an event actually or potentially affects the confidentiality of Navitus Member data.

Training and Education

Navitus is required to provide certification upon request to Federal authorities that certain actions have been completed by vendors, contractors, associates and business entities, Participating Pharmacies, and entities that contract on behalf of Participating Pharmacies.

Navitus requires all pharmacy personnel (employed/contracted) and vendors to complete a CMS-approved or equivalent annual training program that educates the staff with regard to compliance and fraud, waste and abuse. Pharmacy must:

- Provide annual training for staff that includes information on how to mitigate and identify fraud, waste and abuse and address HIPAA Rules, Compliance, False Claims and Anti-kickback Laws and regulations
- Provide training to all owners and personnel about the False Claims Act (31 U.S.C. §3729-33) and Whistleblower Protections available under the Law if the pharmacy receives or makes annual Medicaid payments of $5 million or more

Evidence of certification includes:

- Materials using CMS-approved or equivalent education that meets the requirements regarding compliance and fraud, waste and abuse[33]
- Logs or other tracking that show training upon hire/contract and **annually** thereafter

[31] 42 CFR §423.564
[32] 42 CFR §423.504(b)(4)(vi)(H)
[33] 42 CFR 422.503 and 422.504 and Medicare Managed Care Manual Chapter 9, Section 50.3.2

False Claims Act[34]

Federal Law requires all providers and other entities that receive or make annual Medicaid payments of $5 million or more to educate their employees, contractors and agents about fraud and false claims Laws and the whistleblower protections available under those Laws.[35]

The False Claims Act imposes liability on anyone who knowingly submits, or causes another to submit, a false or fraudulent claim to the United States. The term "knowingly" includes actions taken with actual intent or one that is taken in reckless disregard or in deliberate ignorance of the truth.

The Act allows a private individual or "whistleblower" with knowledge of fraud (either in the past or the present) against the Federal government, to sue on behalf of the government. This could include the recovery of civil penalties as well as triple damages. In general, the Act covers fraud involving any federally funded contract or program apart from tax fraud.

Navitus does not tolerate fraudulent, wasteful, or abusive activity and will investigate and may report activity to the appropriate regulatory, Federal and State agencies for further action and investigation. Participating Pharmacies are expected to report potential misconduct, wrongdoing, or potential infringements of local, State or Federal Laws to the Navitus SIU.

The fraud examples below are not an all-inclusive list:

Wholesale Fraud:

- Counterfeit and adulterated drugs, labels or NDC codes through black-market purchases
- Inappropriate documentation of pricing information
- Speculative buying
- Radio-frequency identification (RFID) tampering

Pharmacy Benefits Management (PBM) Fraud:

- Prescription Drug shorting
- Failure to offer negotiated prices
- Prescription Drug switching
- Phantom claims
- Failure to reverse claims when prescription orders are returned to stock

Pharmaceutical Manufacturer Fraud:

- Illegal usage of free samples
- Kickbacks, inducements, and other illegal remuneration
- Lack of integrity of data to establish payment/determine reimbursement

[34] 31 USC §3729-33
[35] 45 CFR 152.27

Pharmacy Fraud:

- Forging or altering prescriptions
- Forging or altering Prior Authorization (PA) request forms. Navitus will only recognize prescribers as the source of PA.
- Dispensing expired prescriptions
- Refilling prescriptions erroneously
- Billing brand name drugs when Generic Drugs are dispensed
- Billing with a diagnosis (ICD-10) other than what was provided by the prescriber
- Filling less or more than the prescribed quantity of a drug without authorization
- Billing multiple Payors for the same prescription
- Kickbacks to Members
- Inappropriate financial incentives to individuals or entities

Reporting Investigations and Disciplinary Actions

A Participating Pharmacy must notify Navitus immediately, in writing, if its License(s) and/or permit(s) have been or are in jeopardy of being suspended or revoked for any reason. The Participating Pharmacy must also notify Navitus immediately, in writing, if it receives notice of any proceedings that may lead to disciplinary actions, or if any disciplinary actions are taken against the Participating Pharmacy or any of its personnel, including actions by boards of pharmacy, the Office of Inspector General (OIG) or other regulatory bodies.

Failure to immediately notify Navitus, in writing, of any such investigations or disciplinary actions may result in immediate termination as a Participating Pharmacy. Navitus routinely reviews Exclusion and Preclusion Lists to determine those pharmacies and individuals that are excluded or precluded from health care programs. Claims for Covered Pharmacy Services from any pharmacy that is excluded or precluded from such programs will reject at the point of sale.

Anti-Trust/Anti-Competitive Behavior

Participating Pharmacies are prohibited from engaging in activities that directly solicit members or use intimidation or misrepresentations to members or other pharmacies to compel members to end their service relationship with other pharmacies or force a prescription transfer to the Participating Pharmacy. Such activities may be inconsistent with pharmacy practice and ethics, board of pharmacy standards, member interest and may conflict with other standards such as HIPAA Rules, anti-kickback, or anti-trust regulations. Examples may include but are not limited to:

- A pharmacy employee leaves one pharmacy to work at another pharmacy and brings a patient list for the new pharmacy to solicit members.

- A pharmacy employee receives an inquiry from a member about prescription cost and suggests that the member may be eligible for an off-the-books discount if the member transfers the prescription.
- A pharmacy employee receives an inquiry from a member about prescription coverage and deliberately misleads a member about coverage at another pharmacy.

Improper Payment[36, 37, 38]

This is a payment that was placed on the wrong pharmacy, an overpayment, a payment on an incorrect Member, a duplicate payment, or other payment that was received or applied to a pharmacy in error. Where Navitus identifies Overpayments or Improper Payments to or from pharmacies, staff will initiate recovery of such payments within the lesser of 60 days of discovery or in accordance with client contract requirements, whichever is less. Plans may be notified during this period to approve the recovery.

- Audit may identify errors in billing
- Special Investigations may identify potential fraud, waste, or abuse
- Claims identified as non-covered including but not limited to those for products that are investigational or experimental or used for non-approved indications.
- Finance staff may identify such payments through account reconciliation or pharmacy remittance.
- Pharmacy operations may identify such payments through payment rate monitoring or reports from pharmacies sent to providerrelations@navitus.com with the reason they believe an Overpayment has occurred.

Where a Medicaid Program or State Law prohibit extrapolation of claims, Navitus will not apply this methodology to Overpayments. To clarify further, extrapolation is not to be applied to pharmacy claims.

Reporting Fraud, Waste or Abuse

Let us know if a Member, doctor, dentist, pharmacist, other health care provider or a person receiving benefits is doing something wrong. It could be waste, abuse or fraud, which is against the Law. For example, tell us if someone is:

- getting paid for services that were not provided or necessary

[36] Section 6402(a) of the Affordable Care Act

[37] "Medicare Reporting and Returning of Self-Identified Overpayments." 2016-02-11. Centers for Medicare and Medicaid Services, 23 May 2014. Web. 09 Mar. 2016. https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-11.html

[38] "Medicare Overpayments." Medicare Learning Network ICN 006379 (2015): 1-8. Medicare Overpayments. Centers for Medicare and Medicaid Services, 1 Oct. 2015. Web. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/OverpaymentBrochure508-09.pdf

- refraining from the truth about a medical condition to get medical treatment
- allowing someone else to use an insurance or Medicaid ID
- using another person's insurance or Medicaid ID
- refraining from the truth about the amount of money or resources he or she has to obtain benefits
- presenting a false or forged prescription or verbal order

To report waste, abuse, or fraud:

- For Texas
  - Call the OIG Hotline at 800-436-6184
  - Visit https://oig.hhsc.state.tx.us/ and select "Report Fraud" at the top right of the site to complete the online form
- For all other states, report directly to Navitus:
  - Navitus Special Investigations Unit (SIU) 855-673-6503*
  - SIU@navitus.com
  - Medicare D hotline 800-356-7344*, ext. 4028
  - Navitus Health Solutions, Attention: SIU
    - 1025 West Navitus Drive
      Appleton, WI 54913

*All calls are anonymous.

To report waste, abuse, or fraud, gather as much information as possible.

- When reporting a provider (doctor, dentist, counselor, etc.), include:
  - name, NPI, address and phone number of provider
  - name and address of the facility (hospital, nursing home, home health agency, etc.)
  - type of provider (doctor, dentist, therapist, pharmacist, etc.)
  - names and numbers of witnesses who can help with the investigation
  - dates of events
  - summary of what happened
  - specific details about the waste, abuse, or fraud

- When reporting a patient who is a Navitus Member, include:
  - Member's name
  - Member's date of birth
  - city where person lives
  - prescription number
  - date(s) of events
  - summary of what happened
  - specific details about the waste, abuse, or fraud

Claims—General

Claims Adjudication

Participating Pharmacies must comply with the current HIPAA-defined NCPDP Telecom Standard for pharmacy drug claims, coordination of benefits and related pharmacy services. Navitus will hold harmless and not discriminate against or withhold participation or reimbursement any pharmacist who is acting within the scope of his or her License or certification under applicable Law, solely based on that License or certification. Navitus will allow pharmacies to fill prescriptions for covered drugs ordered by any active, valid and Licensed Practitioner regardless of pharmacy's Network participation.

Claims Source

Services must be dispensed directly from the Participating Pharmacy location to qualify as a clean claim. Navitus prohibits claims billed by a Participating Pharmacy which are dispensed through non-pharmacy third party, or which are delegated by a Participating Pharmacy to be provided a non-pharmacy a third-party provider without Navitus approval. This is not consistent with the member's right of pharmacy choice nor is the Participating Pharmacy directly fulfilling its responsibilities under this manual. This paragraph does not prohibit dispensing to members who may convey their medication/supply to a provider who is using this medication/supply to render a medical service as directed by a member's pharmacy benefit.

Downtime Procedures

Navitus strives to minimize planned adjudication downtime and to resolve unexpected downtime issues quickly.

Customer Care is available to assist pharmacies with maintaining business operations during planned adjudication downtime. During an unexpected interruption, Navitus would employ its Business Continuity Plan, focusing first to recover claims processing and Customer Care phone lines.
During a downtime, we request Participating Pharmacies to dispense necessary medications, receive applicable Member payment amounts and electronically submit when possible. If online submission is not feasible, pharmacies should call the appropriate call center located on the back of the Member's card for assistance with:

- confirming eligibility
- verifying coverage
- copay or other payment information
- the expected time claims processing will resume

Reversals

- Pharmacies are required to complete reversals of the Prescription Drug claim within the same payment cycle as the submission or no later than fourteen (14) calendar days after the claim was adjudicated where prescriptions have not been delivered to or picked up by Member.
- Failure to reverse appropriate claims may result in an audit recovery and recapture of all costs involved in the reversal.
- If unable to reverse a claim online, pharmacies can contact the appropriate call center for assistance. Please see Member card for contact information.

Vacation/Replacement Medication

- Allowances for vacation medication and/or lost, stolen, or forgotten medication varies by Payor benefit design. Some Payors allow vacation quantities while others do not. Please contact the appropriate call center (see Member card for contact information) to obtain individual Member benefit information.

Identification Cards

Payors, Navitus or Navitus' designee will provide Members with Prescription Drug ID cards, to be presented to providers. The following may vary by Payor.

The Member information necessary to file a claim is included on the Prescription Drug ID card (or can be obtained) and is described as follows:

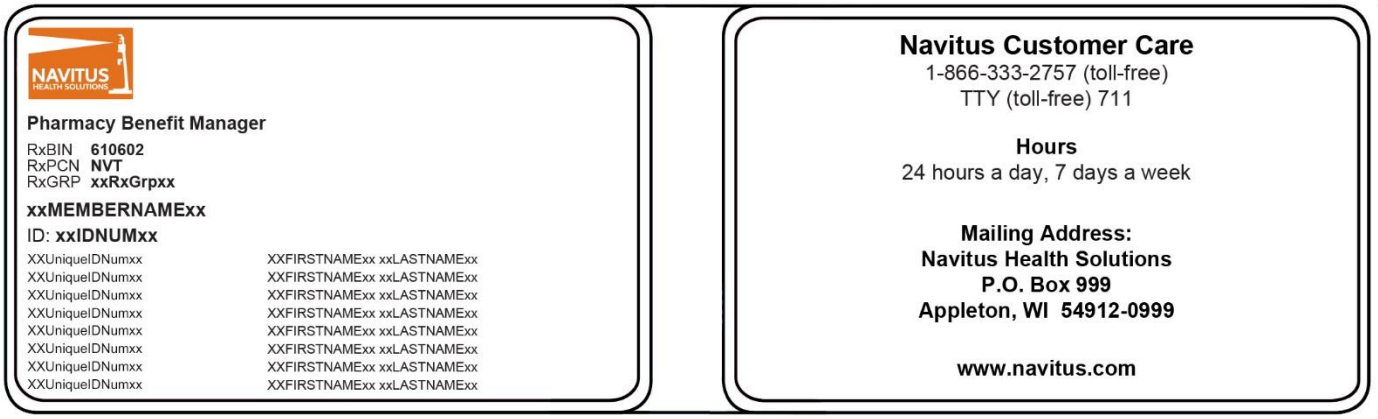
- Cardholder ID—consists of numeric digits or alpha-numeric digits
  - If the ID is not a correct length, the claim will reject "*M/I ID Length*"
  - If the ID cannot find a Member match, the claim will reject "*Non-matched Cardholder ID*"

- Group Number—This field may contain up to 15 alpha-numeric characters that may be required for On-Line Adjudication Processing

- Dependent coverage may include spouse and/or children. Some Payor ID cards may be coded to indicate which family members are covered. Covered family members are identified by the following relationship codes:
  - "1" Cardholder — Eligible Primary Person or Subscriber
  - "2" - Spouse of the Cardholder
  - "3 and following" – Dependent of Primary

Important Note: Use of the correct relationship code is important. Prescription claims must be submitted to Navitus only for the Member for whom the Practitioner has prescribed.

Sample Identification Card:



Navitus expects the Participating Pharmacy to verify the identity of each individual seeking payment for Covered Products. If the person does not have an identification card, but believes s/he is a Navitus Member, the pharmacy can verify eligibility by contacting the Pharmacy Help Desk or by following the instructions on Documents provided by the Member.

Required Pharmacy and Provider Identification Numbers

National Provider Identifier (NPI) is the required pharmacy and Practitioner identifier[39], replacing legacy identifiers[40] on all electronically transmitted claims into Navitus. The NPI is a unique 10-digit identifier assigned to health care providers, such as Practitioners and pharmacies, to use when submitting a HIPAA standard transaction. Navitus requires the use of the NPI in transactions.

- **Pharmacy NPI field**—a pharmacy is required to submit valid and accurate information identifying its Organizational Type 2 NPI in NCPDP field 201-B1 (Service Provider ID) with the qualifier "01" in NCPDP field 202-B2 (Service Provider ID Qualifier)
    - Navitus no longer accepts an Individual Type 1 NPI in the Pharmacy NPI field.

- **Prescriber/Practitioner NPI field**—a pharmacy is required to submit valid and accurate information identifying the Practitioner's Individual Type 1 (Individual) NPI in NCPDP field 444-E9 (Provider ID) along with the qualifier "01" in the NCPDP field 465-EY (Provider ID Qualifier). Organizational NPIs will reject.
    - Navitus routinely monitors claims with Prescriber/Practitioner rejects to ensure accurate and valid NPIs are submitted.

Drug Information Source

[39] Health Insurance Portability and Accountability Act of 1996
[40] NCPDP number, DEA

Navitus contracts with Medi-Span as its source for pharmaceutical prices. In the rare instance where Medi-Span does not publish an AWP or WAC price, Navitus will determine the price from other sources, including, but not limited to, direct published prices or a percentage calculation between AWP and WAC.

Navitus utilizes many drug unit price benchmarks including, but not limited to, AWP, MAC, NADAC, and WAC as set forth in the applicable Participating Pharmacy Agreements for determining reimbursement. For purposes of these terms:

(a) "Average Wholesale Price" or "AWP" means the Average Wholesale Price for a given pharmaceutical product published by Medi-Span and updated in Navitus' systems no less frequently than every seven (7) days beginning with an initial update on January 1 of each year, and

(b) "Wholesale Acquisition Cost" or "WAC" means the Wholesale Acquisition Cost for a given pharmaceutical published by Medi-Span and updated in Navitus' systems no less frequently than every seven (7) days beginning with an initial update on January 1 of each year.[41]

Pharmacy Required to Validate Product Sources

Participating Pharmacy will validate the authenticity of all products purchased for dispensing to Members. Additionally, Participating Pharmacy will fully evaluate all wholesalers and suppliers of Covered Products to ensure compliance with the Law, principles of Good Manufacturing Practices (GMP), Good Distribution Practice (GDP), and ethical conduct. Upon request, Participating Pharmacy will be required to furnish to Navitus i) a list of wholesalers, ii) product pedigree documents, proof of origin of products, or equivalent documentation regardless of whether the products submitted are Prescription Drugs or DME products, including but not limited to diabetic supplies, testing strips, lancets, and glucometers. Specifically, for DME products and any products commonly referred to as specialty drugs, Participating Pharmacy is responsible for ensuring products are purchased from suppliers that are authorized by the respective manufacturer to distribute such products.

[41] 42 CFR §423.505(i)(3)(viii)(A) and (B)

Medicare Part D

Navitus administers support for Medicare Part D Plan Sponsors and manages the Medicare Part D Program requirements and compliance. Therefore, a Navitus Network Pharmacy must comply with all applicable Medicare Laws, regulations and direction of CMS with respect to Medicare Part D Prescription Drug Plans and Medicare Advantage Plans. For information regarding the Medicare Part D Regulatory Requirement, click here.

Medicare Pharmacy Requirements

Any services or activities performed by Participating Pharmacy in connection with these terms shall be consistent and comply with each Payor's contractual obligations to its Medicare Members and CMS.[42]

Participating Pharmacy shall,[43]

- Agree that Participating Pharmacy and its affiliates, subsidiaries, directors, officers, employees, and agents are bound by the program provisions.[44]
- Ensure that possession of the appropriate Part D Drug is transferred to each Medicare Member,
- Verify the individual's eligibility by reviewing the individual's identification card each time a prescription is filled,
- Participating pharmacy must maintain accurate patient medical records including Member contact information, allergies, and present residence at time of service.
- Check its computer for information transmitted by Navitus about the individual's coverage, to perform quality assurance activities[45]
- Measure or mix Part D Drug consistent with the underlying prescription orders,
- Fill containers for Part D Drug when appropriate,
- Physically provide completed prescriptions to Medicare Member and to maintain the facility and equipment necessary to operate each pharmacy location.
- Submit claims for Covered Pharmacy Services to Navitus on behalf of Medicare Members whenever the identification card is presented or on file at the Participating Pharmacy unless the Medicare Member expressly requests that a particular claim not be submitted to the Part D Payor[46]
- Verify via real time, via On-Line Adjudication Processing, whether an original or refill prescription from a Medicare Member is a Part D Drug, and follow any instruction communicated at the point-of-sale by or on behalf of Navitus, including, but not limited to, whether the Prescription Drug is a Part D Drug, the then-current reimbursement amount for a

[42] 42 CFR §423.505(i)(3)(iii)
[43] 42 CFR §423.100
[44] 45 CFR Part 76
[45] 42 CFR §423.153(c)(2),
[46] 42 CFR §423.120(c)(3).

covered Part D Drug and applicable Cost Sharing Amount to collect from the Medicare Member.[47]

- Agree not to hold any Medicare Member liable for payment of any fees owed by Navitus or any Payor to Participating Pharmacy. In no event shall Participating Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, file or threaten to file with a credit reporting agency, or have any recourse against a Medicare Member or person acting on the Medicare Member's behalf, for Part D Drugs and related Covered Pharmacy Services provided pursuant to these terms.[48]

First Tier, Downstream, and Related Entity (FDR) Manual. Any Participating Pharmacy who serves Medicare patients and has a signed contract addendum with Navitus for Medicare Members is recognized as a downstream vendor under the Medicare Part D Drug Program. Therefore, Participating Pharmacy must comply with the FDR Compliance Requirements including but not limited to training requirements, reporting for offshore subcontractors, exclusion screening, record retention, reporting compliance issues, and standards of conduct. This manual reference can be found online at https://www.navitus.com/vendor-fdr.

Disclosure of Price Differentials. Participating Pharmacy agrees to inform all Medicare Members receiving a Part D Drug of any differential between the price of that drug and the price of the lowest priced generic version of that Part D Drug that is therapeutically equivalent and bioequivalent and available at Participating Pharmacy, unless the particular Part D Drug being purchased is the lowest priced therapeutically equivalent and bioequivalent version of that drug available at Participating Pharmacy.[49] Participating Pharmacy further agrees to provide Medicare Members such information after the Part D Drug is dispensed at the point of sale. Participating Pharmacy further agrees to provide Navitus such information promptly and in a format acceptable to Navitus, for inclusion in a written explanation of benefits on behalf of each Payor to be provided to such Medicare Members.[50] "Prescription Drug Pricing Standard"[51] shall mean any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts that are based upon Average Wholesale Price, Wholesale Acquisition Cost, average manufacturer price, average sales price, Maximum Allowable Cost, or other cost, whether publicly available or not. Navitus agrees to update and disclose to Participating Pharmacy in advance of use Prescription Drug Pricing Standard for which Navitus solely determines such unit price for use for reimbursement of claims.[52]

[47] 42 CFR 423.100 and 42 CFR §423.104(g)
[48] 42 CFR §423.505(g) and (i)(3)(i)
[49] 42 CFR §423.132
[50] 42 CFR §423.132(a) and (d)(1)
[51] 42 CFR §423.501
[52] 42 CFR §423.505(i)(3)(vii)

Offering Covered Part D Drugs at the Calculated Price. Participating Pharmacy shall offer Part D Drugs to Medicare Members at the lessor of the applicable Calculated Price, the Usual and Customary Price, or the gross amount due. Participating Pharmacy shall charge a Medicare Member only the lessor of the applicable Calculated Price, the Usual and Customary Price, or the gross amount due, and no more, for a Part D Drug dispensed by Participating Pharmacy to the Medicare Member, even when a Payor may have no financial responsibility toward the payment of such drug.

Delegation of Duties. Navitus shall have the right, on behalf of its Payors, to delegate certain activities, duties and responsibilities to Participating Pharmacy.[53] Any such delegation by Navitus shall be in writing, shall specify the delegated activities, duties and reporting responsibilities and shall be subject to on-going monitoring by Navitus.[54] In the event that Navitus, a Payor or CMS determines that Participating Pharmacy has failed to perform satisfactorily any or all such activities, duties or responsibilities, then Navitus shall have the right to notify Participating Pharmacy in writing and allow Participating Pharmacy an opportunity to cure such performance within thirty (30) days of receipt of such notice unless: (a) otherwise directed by CMS or a Payor; (b) Participating Pharmacy has failed to perform satisfactorily in the past; or (c) an opportunity to cure such performance is not, in the sole discretion of Navitus, practicable. In the event that Participating Pharmacy does not cure such performance, then such delegation shall terminate as of the end of such thirty (30) day period. In the event that Participating Pharmacy fails in the sole discretion of Navitus to cure such performance as of the end of such thirty (30) day period, then Navitus shall have the right to suspend, revoke or terminate all or any portion of the decision to delegate such activities, duties, or responsibilities. In addition, Navitus, on behalf of applicable Payors, or CMS shall have the right to institute corrective action plans or seek other remedies or curative measures consistent with applicable Law.

Participating Pharmacy shall not delegate any duties, activities or responsibilities required of it under these terms, to an affiliate or third party, without the prior written approval of Navitus, on behalf of applicable Payors. Any such approved delegation (an "Approved Delegation") shall be performed by the delegate in accordance with the applicable Payors' contractual obligations to CMS and Participating Pharmacy's obligations under these terms. Participating Pharmacy agrees that any Agreements of Participating Pharmacy with respect to an Approved Delegation shall be in writing, signed by the parties to be bound thereby and in compliance with all applicable Law and CMS instructions and shall not relieve Participating Pharmacy of liability for any duties, activities, or responsibilities subject to such Approved Delegation. In the event that a delegate of Participating Pharmacy has failed to perform satisfactorily any or all such sub-delegated duties, activities, or responsibilities then Navitus, the applicable Payor or CMS shall have the right to suspend, revoke or terminate such Approved Delegation effective upon the date set forth in a written notice furnished to Participating Pharmacy. In addition, Navitus, on behalf of applicable Payors, or CMS shall have the right to institute corrective action plans or seek other remedies or curative measures respecting the

[53] 42 CFR §423.505(i)(4).
[54] 42 CFR §423.505(i)(4)(iii).

unsatisfactory Approved Delegation consistent with applicable Law. Any attempted sub-delegation by Participating Pharmacy that is not an Approved Delegation shall be null and void and of no force or effect.

Transition Policy

CMS requires all Part D plans to provide a transition supply to Part D-eligible persons during their transition periods (within 90-days of their eligibility for a transition benefit). The intent is to provide immediate short-term coverage for new Part D enrollees in order to continue ongoing therapies. Transition period is triggered by the following:

- New eligibility
- Formulary changes
- Admittance, readmittance or discharge from a facility which requires accurate submission of Patient Residence Code

- At retail, Medicare Members are limited to a one time 30-day transitional fill of a non-Formulary drug during the transition period.
- Long-term care Medicare Members are eligible for multiple fills, limited to a 31-day supply per fill, during the entire length of the 90-day transition period.
- Pharmacies should be alert to their POS messaging systems during a transition period. Alerts indicate when a drug will no longer be covered.

Medicare Part A, B and D Coordination of Benefits

- A pharmacy that provides services to Members who are eligible for both Medicare and Medicaid, shall not hold Medicare Members financially responsible for Medicare Copayments, Coinsurance or Deductibles when Medicaid is responsible for payment of such amounts.
    - In addition, as applicable to such claims for such Part D-eligible persons, the Member's pharmacy shall accept the Payor's designated Medicare payment amount for services as payment in full or to bill the appropriate State Medicaid source.
    - This requirement shall not prohibit the pharmacy from collecting the cost-sharing amount from a Medicare Member for a non-Part D covered drug delivered on a fee-for-service basis to any Part D eligible person, where payment has not otherwise been paid by a primary or secondary carrier, in accordance with regulatory standards for coordination of benefits.
- A pharmacy that dispenses prescriptions to Medicare Members during covered inpatient stays at skilled nursing facilities shall bill claims under Medicare Part A and ensure that Medicare Members coverage under Medicare Part A has been exhausted before billing Medicare Part D Plan Sponsors.
- The pharmacy understands and agrees that if Navitus becomes aware of billed prescription claims for reimbursement under Medicare Part D that should have been billed under Medicare Part A or B, Navitus shall reverse such claims on behalf of Payors who are Part D Plan Sponsors,

withhold any amounts due from such reversed claims, and require the pharmacy to refund Medicare Members that inappropriately paid any Part D cost share.

Best Available Evidence (BAE)

Pharmacies are to work with the Part D Plan Sponsor, not Navitus, to obtain appropriate documentation to allow for subsidy status. For Navitus MedicareRx EGWP Medicare Members, Navitus Customer Care is the appropriate initial point of contact for best available evidence.

Part D Plan Sponsors are required to accept any of the following forms of evidence to establish the subsidy status of a full benefit dual-eligible Medicare Member when provided by the Medicare Member or the Medicare Member's pharmacist, advocate, representative, Member's family or other individual acting on behalf of the Medicare Member:

- a copy of the Medicare Member's Medicaid card that includes the Medicare Member's name and an eligibility date during a month after June of the previous calendar year
- a copy of a State Document that confirms active Medicaid status during a month after June of the previous calendar year
- a printout from the State's electronic enrollment file showing Medicaid status during a month after June of the previous calendar year
- a screen print from the State's Medicaid system showing Medicaid status during a month after June of the previous calendar year
- other documentation provided by the State showing Medicaid status during a month after June of the previous calendar year
- a copy of the SSA award letter for individuals who are not deemed eligible, but who apply and are found to be eligible for the low-income subsidy

Low Income Subsidy (LIS) or Other Hardship

Pharmacies are to work with the respective Medicare Part D Plan Sponsor, to obtain appropriate documentation to allow for subsidized cost-sharing considerations, if the pharmacy believes the Medicare Member is eligible for lower cost sharing. For Navitus MedicareRx EGWP Medicare Members, Navitus is the appropriate initial point of contact for best available evidence.
Part D Plan Sponsors are required to accept any one of the following forms of evidence from Medicare Members or pharmacists to establish that a Medicare Member is institutionalized and qualifies for zero cost sharing:

- a remittance from the facility showing Medicaid payment for a full calendar month for that individual during a month after June of the previous calendar year.
- a copy of a State Document that confirms Medicaid payment on behalf of the individual to the facility for a full calendar month after June of the previous calendar year; or
- a screen print from the State's Medicaid system showing that individual's institutional status based on at least a full calendar month stay for Medicaid payment purposes during a month after June of the previous calendar year.

- Effective as of a date specified by the Secretary, but no earlier than January 1, 2012, a copy of:
  - a) A State-issued Notice of Action, Notice of Determination, or Notice of Enrollment that includes the beneficiary's name and HCBS eligibility date during a month after June of the previous calendar year
  - b) A State-approved HCBS Service Plan that includes the beneficiary's name and effective date beginning during a month after June of the previous calendar year
  - c) A State-issued prior authorization approval letter for HCBS that includes the beneficiary's name and effective date beginning during a month after June of the previous calendar year
  - d) Other documentation provided by the State showing HCBS eligibility status during a month after June of the previous calendar year
  - e) A state-issued document, such as a remittance advice, confirming payment for HCBS, including the beneficiary's name and the dates of HCBS.

When one of the forms of the BAE listed above is presented, the pharmacy is to provide the Medicare Member access to covered Part D Drugs at a reduced Cost Sharing level that is no greater than the higher of the LIS Cost Sharing level for full subsidy or zero cost-sharing if the BAE also verifies the Medicare Member's institutional status.

According to CMS guidance, the CMS-contracted Medicare Part D Prescription Drug Plan (PDP) should work with Participating Pharmacies to provide them with direct reimbursement for any Cost Sharing Amounts not collected from LIS-eligible enrollees. Before Cost Sharing reimbursements are made for Medicare Members that are deemed LIS-eligible and/or living in long-term care facilities, plans must ensure that the pharmacies in question have not collected Cost Sharing amounts, waived Cost Sharing amounts, and are carrying a debt for the amounts incorrectly charged to Medicare Members.

To ensure Navitus accurately reimburses a pharmacy or a Member, Navitus requires the pharmacy to complete an attestation that instructs Navitus whether the pharmacy collected a Cost Sharing Amount from an LIS-eligible enrollee. Navitus uses the information provided on the attestation to determine if the Member or the pharmacy is to be reimbursed for the outstanding debt.

CMS Standardized Notice (CMS-10147) (OMB 0938-0975)

The Centers for Medicare and Medicaid Services (CMS) requires Medicare network pharmacies to issue the "Medicare Prescription Drug Coverage and Your Rights" notice to Medicare enrollees each time an enrollee is denied coverage, and/or disagrees with cost-sharing information and the issue cannot be resolved at point of sale.[55] The notice must be provided if the pharmacy receives a reject claim transaction response (reject 569) that indicates the claim is not covered by the Medicare Part D benefit.

[55] 42 CFR §423.562(a)(3) and §423.128(b)(7)(iii)

Navitus requires Medicare Part D Participating Pharmacies (including retail, long-term care, home infusion, mail order and specialty) to complete and return an attestation, which confirms the pharmacy is in compliance with the CMS requirement, upon entering into a contract with Navitus.

ATTESTATIONS can be obtained by contacting Navitus' Credentialing Team at 608-298-5776 or at credentials@navitus.com.
A Medicare Part D Participating Pharmacy found to be out of compliance with the notice requirement will be provided an opportunity to become compliant and provide proof of providing the standardized notice. If the Medicare Part D Participating Pharmacy has failed to provide proof, the pharmacy may be subject for suspension or termination from the Medicare network.

Auto-Ship and Refill Programs

Auto-Ship

Navitus requires Participating Pharmacies to obtain Member authorization prior to filling a new or refill Medicare prescription. This helps control fraud, waste and abuse and ensures that Medicare Members receive only new prescriptions and refills that are requested.[56]

Auto Refill

Participating Pharmacies that use an automated fill program to improve adherence for Covered Products, must confirm with the Member or Member's caregiver or representative, prior to dispensing, that a refill be dispensed.

Further, Participating Pharmacies must complete a drug regimen review on all prescriptions filled as a result of the auto-fill program. The auto-fill program will not affect pharmacies when the Member or the Member's caregiver or representative picks up the prescription.

Participating Pharmacies can continue to use their auto-fill programs provided the following apply:

- Member participation in the automatic delivery program is voluntary and opt-in only. Documentation of this opt-in must be on file.
- The prescription is for refills. New prescriptions that are e-prescribed, faxed, mailed, or phoned-in to the pharmacy, even if the new prescription is a continuation of existing therapy, do not apply.
- Participating Pharmacy provides a minimum of two shipping reminders, which includes name of medication, scheduled shipping date/range, how to determine cost of medication and information on how to cancel the order prior to shipping.
- Participating Pharmacy has easy-to-locate and easy-to-understand Medicare Member materials on how to disenroll from auto-fill programs, and the pharmacy responds promptly to all disenrollment requests.

[56] 42 CFR §423.504

- The Participating Pharmacy confirms at least annually that the Member chooses to continue the automatic-fill program and upon receipt of each renewed prescription from a Practitioner, even if the new prescription is a continuation of existing therapy.
- The Participating Pharmacy promptly discontinues automatic fill upon notification that a Medicare Member entered a skilled nursing facility or elected hospice coverage.
- The Participating Pharmacy promptly discontinues automatic fill at the request of the Member or his or her caregiver or representative.
- The Participating Pharmacy will refund the patient or payor for any prescription refilled through automatic fill if the pharmacy was notified that the patient wished to be removed from the automatic fill program, regardless of the reason, or the Participating Pharmacy was notified of request for disenrollment from the program before dispensing.

This policy limits unintended waste and costs by ensuring Members (or the Member's caregiver or representative) confirm that a prescription should be filled.

This criterion does not prevent pharmacies from utilizing a refill-reminder program that requests Members to pick up their prescriptions. Also, auto-fill criteria do not apply to long-term-care pharmacy dispensing and deliveries.

Home Infusion (MEDD)

The following terms apply with regard to home infusion services including those provided to Medicare Members who receive benefits governed by CMS rules and regulations. "Home Infusion" means the administration of covered Drugs using intravenous, subcutaneous, and epidural routes (into the bloodstream, under the skin or into the membranes surrounding the spinal cord).

1. **Services.** Participating Pharmacy agrees that any services or activities performed by Participating Pharmacy in connection with these terms shall be consistent and comply with each Payor's contractual obligations to its Members and CMS.[57] Participating Pharmacy agrees to ensure that possession of the appropriate Drug is delivered to each Member in a usable form, to verify the individual's eligibility each time a prescription is filled, to check its computer for information transmitted by Navitus about the individual's coverage, to perform quality assurance activities, to measure or mix (i.e., reconstitute or compound) consistent with the underlying prescription orders, to fill containers for Drugs when appropriate, to physically provide completed prescriptions to Members and to maintain the facility and equipment necessary to operate each pharmacy Location.[58],[59] Participating Pharmacy further agrees that all Drugs delivered to Members for use in their home infusion therapy shall be in a form that

[57] 42 CFR §423.505(i)(3)(iii)
[58] 42 CFR §423.100
[59] 42 CFR §423.153(c)(2),

can be administered in a clinically appropriate fashion and shall not be delivered to Members in an unmixed, unusable form. Participating Pharmacy further agrees not to dispense to any Member any drug, for which Participating Pharmacy has obtained pricing or discounts under Section 340B of the Public Health Services Act.[60]

2. **Quality Assurance Activities.** Participating Pharmacy agrees in connection with the quality assurance activities referenced above, to review the prescribed drug therapy before each Drug is dispensed. Such quality assurance activities shall include, but are not limited to, (i) screening for potential drug therapy problems due to therapeutic duplication, (ii) age/gender-related contra-indications, (iii) over-utilization and under-utilization, (iv) drug-drug interactions, (v) incorrect drug dosage or duration of drug therapy, (vi) drug-allergy contraindications, (vii) clinical abuse/misuse, (viii) ongoing clinical monitoring and care coordination services; and (ix) ensuring that all ancillary professional services and ancillary supplies are in place for each Member before dispensing Drugs to each such Member.

Access to Home Infusion Pharmacies. Access to home infusion pharmacies to provide Medicare Members convenient access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions[61,62].

Participating Pharmacy:

i. Meets Medicare requirements for Medicare Members[63]
ii. Is capable of delivering home-infused drugs in a form that can be administered in a clinically appropriate fashion.
iii. Is capable of providing infusible Drugs for both short-term acute care and long-term chronic care therapies.
iv. Ensures that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing home infusion drugs.
v. Provides delivery of home infusion drugs within 24 hours of discharge from an acute care setting, or unless the next required dose as directed by the Prescriber is required to be administered later than 24 hours after discharge.

Long-Term Care

Long-term-care (LTC) pharmacies with (Short-Cycle Dispensing) are required to dispense solid oral doses of brand-name drugs, specified by CMS, to Members residing in LTC facilities in no greater than

[60] 42 USC §256b
[61] 42 CFR §423.120(a)(4)
[62] Medicare Modernization Act and its implementing regulations
[63] 42 CFR §423.120(a)(4)

14-day increments, except to the extent such requirements have been waived, as specified by applicable Medicare regulations.[64]

Long-term-care and home-infusion pharmacies must submit values in the following NCPDP telecommunication standard fields:

NCPDP FIELD	NCPDP FIELD NAME
384-4X	Patient Residence
307-C7	Place of Service
147-U7	Pharmacy Service Type

Participating Pharmacies can find more information regarding the submission of claims for LTC and home infusion on the Payor sheets found on Navitus' website https://pharmacies.navitus.com/.

Information necessary to identify LTC or home infusion dispensing:

NCPDP Segment	NCPDP Field	NCPDP Field Name	Value
Insurance	997-G2	CMS Part D Defined Facility	Y
Patient	384-4X	Patient Residence	00-Not Specified 01-Home 02-Skilled Nursing Facility 03-Nursing Facility 04-Assisted Living* 05-Custodial Care Facility (MED B use only) 06-Group Home 09-ICFMR* 11-Hospice 15-Prison/Correctional Institution
Patient	307-C7	Place of Service	01-Pharmacy 02-Telehealth 03-School 04-Homeless Shelter
Claim	147-U7	Pharmacy Service Type	01-Community/Retail

[64] 42 CFR § 423.154

NCPDP Segment	NCPDP Field	NCPDP Field Name	Value
			03-Home Infusion 05-Long Term Care 06-Mail Order 08-Specialty Care
Claim	420-DK	Submission Clarification Code	Refer to Chart Below

*ICF/IID (Intermediate Care Facilities for Individuals with Intellectual Disabilities) and Assisted Living Facilities are exempt from short-cycle dispensing.

Submission Clarification Code Values of High Risk and Extra Monitoring:

NCPDP Code/Value	NCPDP Description	NCPDP Explanation
16	LTC Emergency Box (kit) or automated dispensing machine	Indicates that the transaction is a replacement supply for doses previously dispensed to the patient after hours
18	Long Term Care Patient Admit/Readmit Indicator	Indicates that the transaction is for a new dispensing of medication due to the patient's admission or readmission status.
21	LTC dispensing: 14 days or less not applicable	Fourteen day or less dispensing is not applicable due to CMS exclusion and/or manufacturer packaging may not be broken or special dispensing methodology (i.e., vacation supply, leave of absence, ebox, splitter dose). Medication quantities are dispensed as billed
36	LTC dispensing: dispensed outside short cycle	Claim was originally submitted to a Payor other than Medicare Part D and was subsequently determined to be Part D

Audits

Navitus reserves the right to audit LTC Network Pharmacy Providers. Requests may include, but are not limited to, prescription files, records and signature logs or approved proof-of-delivery records. Proof-of-delivery for claims should be consistent with and maintained according to Laws and program guidelines including those for Medicare.[65]

[65] 42 CFR § 424.57(c)(12) and Medicare Program Integrity Manual Chapter 4, Section 4.26

Navitus is tasked with collection of documentation for Acumen, Financial and other CMS administered audit reviews. For those audits, Navitus will request the required documents through written communications. The due dates and turn-around times may be shorter than the normal audit cycle and will be specified in the audit request. CMS does not generally supply results of these audits to Navitus or the pharmacies.

Pharmacies should respond timely with clearly labeled documents to avoid delays and further inquiries.

For LTC claims, Navitus follows the CMS established guidelines and requires the following to be included on the hard copy or physician orders:

- Member name
- drug name and strength
- DAW if applicable
- Practitioner name
- Practitioner signature
- order date
- specific directions for use

**Prescription orders must be current for the fill date specified. Standing orders that are greater than one-year-old will not be accepted.

Acceptable forms of supplemental documentation may include:

- An unsigned Medication Order for a controlled substance accompanied by supplemental information, such as a physician-signed page from the medical chart referencing review of order in progress notes
- A dictation note in a medical chart stating orders have been reviewed and approved by a physician
- A provider chart review log showing that a provider with prescriptive authority reviewed and approved a beneficiary's medication order
- A completed and signed Physician Attestation Form

Unacceptable stand-alone documentation includes:

- Prescription history only
- Pharmacy attestation
- Pharmacy transaction files
- Pharmacy Drug Utilization Review (DUR) Reports
- Pharmacy software screenshot
- Signature log
- Pharmacy micro-tag
- Refill requests that do not contain the required elements listed above

- Internal audit reports
- Packing lists
- MAR forms

Prescription Payment Plan

CMS' Medicare Prescription Payment Plan ("M3P"), which was established under the Inflation Reduction Act of 2022 ("IRA"), requires Medicare prescription drug plans to offer Part D enrollees the option to pay their out-of-pocket Part D drugs costs through monthly payments over the course of the plan year instead of as upfront payments at the pharmacy point of sale ("POS") beginning January 1, 2025. Pursuant to section 1860D–2(b)(2)(E)(v)(III)(ee) of the IRA, a Participating Pharmacy must provide notice to Part D enrollees identified as "likely to benefit" from the M3P program, also called a "Medicare Prescription Payment Plan Likely to Benefit Notice."

If a Part D enrollee is identified through the pharmacy notification process as likely to benefit, outreach and notification must be provided at the pharmacy POS. CMS has developed a standardized notice to be provided to Part D enrollees identified as likely to benefit from the M3P program, in addition to other M3P materials. To access these materials, please visit the CMS website: https://www.cms.gov/files/zip/medicare-prescription-payment-plan-model-materials.zip

PCI Compliance Adds:
Pharmacies who take credit cards must follow the Payment Card Industry Data Security Standards (PCI DSS). These standards prevent the use of credit card data, security code, and other transaction information from being recorded outside of the payment system for credit cards. Your pharmacy should ensure that information regarding a credit card transaction is not being included a claim submission, email or other written or electronic communication. This information may not be adequately protected or meet the PCI DSS rules. For more information, you can learn more about the pharmacy's responsibilities under PCI Security Standards Council – Protect Payment Data with Industry-driven Security Standards, Training, and Programs

Claims—Submission of Claims

Participating Pharmacy shall transmit to Navitus in accordance with the On-Line Adjudication Processing requirements, all claims for payment of Covered Pharmacy Services unless otherwise agreed upon in writing by Navitus.

BIN-PCN-Payor Sheets

Minimum required fields for claims submission: (required fields are subject to Plan Specifications)

BIN: 610602 (from ID Card)	PCN: (from ID Card)
Group (from ID Card)	Member ID (from ID Card)
Date of Birth	Gender
Relationship Code	Pharmacy NCPDP
Rx Number	NDC
Quantity	Date Filled
U&C	Gross Amount Due (GAD)

Payor Sheets are available at https://pharmacies.navitus.com/

Member Information (demographics, residence codes, allergies, etc.)[66]

Participating pharmacy must maintain accurate patient medical records including Member contact information, allergies, and present residence at time of service.

Claim Edits

Following an online claim transmission by a pharmacy, the Navitus adjudication system will return a response to indicate the outcome of processing. If the claim passes all edits, a "Paid" response will be returned with the Navitus-allowed amount for the paid claim. A "Rejected" response, along with NCPDP rejection codes, will be returned when a claim fails one or more edits.

Quantity Dispensed

Participating Pharmacies **must** dispense the quantity authorized by the Practitioner and as allowed by State Law or up to the plan limitation. For proper reimbursement, the actual and allowed quantity dispensed to the Member should be submitted in the "Quantity Dispensed" field (442-E7).

Many NDC numbers are packaged in sizes that are not whole numbers. When entering a claim for a drug that is packaged in a metric decimal-sized package (e.g., 1Ø.6 or 2.5), pharmacies must submit the exact metric decimal on the claim. Do not round up or down.

[66] Medicare Pharmacy Requirements

Examples:

Flovent HFA 44mcg	Xalatan Sol 0.005%
Representative NDC 00173071820	Representative NDC 00013830304
One Inhaler dispensed (1 x 10.6)	One bottle dispensed (1 x 2.5)
Quantity Dispensed field = 10.6	Quantity Dispensed field = 2.5

- If a prescription is written for a quantity of one for eye drops, inhalers and topical agents, pharmacies should dispense the smallest commercially available product.
- If a larger package size is dispensed, an appropriate reason must be verified with the Practitioner and Documented on the hard-copy prescription or within another readily retrievable system and provided during an audit.

Three standard billing units used to describe drug products:

- EA—each
- ML—milliliters
- GM—grams

Products measured in units and not by weight or volume are billed as the number of "each" dispensed.

- Typical dosage forms are tablets, capsules, transdermal patches, non-filled syringes and reconstitutable injectable vials. These forms should be expressed as the number of units dispensed in the Quantity Dispensed field.
    - Example: 30 tablets dispensed
        - Quantity Dispensed field = 30
    - Example: 30 insulin syringes dispensed
        - Quantity Dispensed field = 30

Products, such as solutions and injectable liquids, measured by liquid volume are billed as the number of milliliters dispensed.

- Typical dosage forms measured by liquid volume can include liquids, suspensions, solutions, IV solutions, irrigations, nasal sprays, oral inhalers, reconstituted non-injectable liquid dosage forms, etc., and should be expressed as the exact number of milliliters dispensed, including metric decimal-quantity amounts in the Quantity Dispensed field.
    - Example: Enoxaparin 40mg/0.4ml syringes
        - 17 syringes dispensed (17 x 0.4)

        - Quantity Dispensed field = 6.8
    - Example: Ipratropium Bromide 0.02%, 2.5 mL/nebule
        - Report quantity dispensed in exact milliliters multiplied by the number of nebules dispensed
        - 25 nebules dispensed (2.5 x 25)
        - Quantity Dispensed field = 62.5

    - **Exception:** Cimzia® Kit
      Representative NDC 50474070062
      One kit dispensed
        - Report quantity of kits dispensed in the Quantity Dispensed field
        - Quantity Dispensed field = 1

Oral antibiotic suspensions, eye drops, and other non-injectable dosage forms that require reconstitution prior to dispensing and are labeled by volume, should be expressed in milliliters.

- These products should be expressed with the exact number of milliliters, including the metric decimal-quantity amounts, in the Quantity Dispensed field.
    - Example: Amoxicillin Suspension 150 mL (150 x 1)
      One 150-mL bottle dispensed
      Quantity Dispensed field = 150

Products measured by weight are billed as the number of "grams" dispensed and are labeled with grams on the product.

- Products measured by weight can include ointments, creams, balms, bulk powders, inhalers, etc., and should be expressed as the exact number of grams dispensed, including metric decimal-quantity amounts in the Quantity Dispensed field. Pharmacies should attempt to dispense trade-package sizes only and not bill for partial tubes.

    - Example: Betamethasone Valerate Cream 15 gm
      One 15-gm tube dispensed
      Quantity Dispensed field = 15

    - Example: Bacitracin Ophthalmic Ointment 3.5 g
      One 3.5-gm tube dispensed
      Quantity Dispensed field = 3.5

    - Example: Androgel® Gel Packet
      Representative NDC 00051842530

Dispensed 30 packets containing 2.5 gm each (30 packets x 2.5 gm)
Quantity Dispensed field = 75

- **Exception:** Pulmicort Flexhaler® 180 mcg
  Representative NDC 00186091612
  One Flexhaler dispensed
  Quantity Dispensed field = 1

Additional Clarification

- Quantities dispensed from a partially filled container should indicate the amount of fill volume containing the actual drug and should be expressed in milliliters.

  - Example: Dextrose 5% 250 mL in a 500-mL bottle
    Quantity Dispensed field = 250

Powder-packet products, such as Questran®, should be expressed by number of packets dispensed.

  - Example: Questran®
    Representative NDC 49884093665
    60 packets dispensed
    Quantity Dispensed field = 60

- Enemas labeled volumetrically, should have the quantity dispensed expressed in milliliters.

  - Example: Rowasa®
    Representative NDC 68220002207
    7 enemas dispensed: 60 mL per enema (60 x 7)
    Quantity Dispensed field = 420

  - If the enema is not labeled volumetrically, the quantity dispensed would be expressed as the number of units dispensed.

- Combination drug products packaged with more than one drug in different dosage forms should be expressed as units of 1 kit.

  - Example: Clindareach®
    Representative NDC 65880050302
    Package contains: pledgets, appliqués, cleansing pads and applicator.
    Quantity Dispensed field = 1

- Example: Duac CS® Convenience Kit
  Representative NDC 00145236701
  Package contains 2 different products
  Quantity Dispensed field = 1

- Convenience packets, therapy packs and prepackages must be billed as the number of individual tablets or capsules (units) dispensed and not the number of boxes or packages.
  - Example: Chantix® Starting Month Pak
    Representative NDC 00069047197
    Package size = 53 tablets
    Quantity Dispensed field = 53

  - **Exception:** Prevpac® Patient Pack
    Representative NDC 64764070201
    Package size = 14 doses (each dose = 2 Prevacid 30 mg caps, 4 amoxicillin 500 mg caps and 2 clarithromycin 500mg tabs)
    Quantity Dispensed field = 112

Unbreakable Packages

An unbreakable package, also referred to as a unit-of-use package, is a prescription medication that cannot be sub-divided into fewer dispensed quantities or contains a quantity designed and intended to be dispensed directly to a Member for a specific use without modification, except for the addition of a prescription label by a dispensing pharmacist (e.g., sterile eye drops, respiratory inhalers, insulin vials, etc.).

Pharmacies should bill for multiples of whole packages with the true Days' Supply and allow the claim to reject before reducing the Days' Supply and/or quantity. If the order is written for a quantity that calculates to be greater than the plan will allow, the quantity must be reduced to meet the plan limits. Navitus will allow pharmacies to round down to the max Days' Supply when 50% or greater of the final unbreakable package is needed to reach the max Days' Supply.

- Drops example: Order is written for 10ml. One 5ml bottle of eye drops is a 20-day supply and the max day supply for the plan is 30. Navitus will allow two 5ml bottles or one 10ml bottle to be billed as a 30-day supply, since 50% of the second bottle will be used to reach 30 days. Pharmacies should refill, if allowed, based on true Days' Supply of 40.

- Test strip example: Three 50-count boxes of test strips is a 37.5-day supply. Pharmacies should reduce the quantity to two 50-count boxes as a 25-day supply, because only 20 strips of the third 50-count box (40%) will be used by the maximum 30-day supply allowed.

Insulin pens: Recent updates to the manufacturer's packaging include a statement about dispensing in the original sealed cartons only. If Pharmacy chooses to open the carton, such as in LTC settings, you will not be subject to recovery if the submitted claim is accurate. Navitus prefers splitting the cartons to aid in member adherence and mitigation of waste. Pharmacies should always calculate and bill the true day supply and may reduce the day supply per the plan limitations if a *7X-Day Supply Exceeds plan limitation* rejection is received.

Effective 7/1/2020, for most Commercial and Exchange plans, Navitus will allow pharmacies to enter in Submission Clarification Code (SCC) of 10 to permit a rejected claim to pay, up to a maximum of 140 days. Your pharmacy will be notified of this option through our additional messaging which will state, "*Pharmacy may submit with the true day supply by using Submission Clarification Code 10.*" Please note that additional member copays will apply. This SCC code will not override formulary restrictions or step therapy requirements.

NOTE:

- In all situations, the pharmacy must refill according to the true day supply and not the billed day supply.
- Navitus recommends not utilizing auto refill programs for these claims as this may result in overfilling and recoveries due to refill too soon.
- Per 12.02(b)(6) of the Participating Pharmacy Agreement pharmacies are not to use automatic refill dispensing without the express consent of the Member and Navitus.

Days' Supply

NCPDP's "Days' Supply" field (4Ø5-D5) is a key field referenced for Drug Utilization Review (DUR) and Early Refill edits. An incorrect Days' Supply can result in inaccurate DUR alerts and cause claims to reject for early refill. Navitus requires Participating Pharmacies to use the following method to determine proper Days' Supply:

Quantity ÷ total dosage units per day = # of days medication will last Member

A 30-day supply is no longer standard. Many plan benefits permit extended days' supplies. Pharmacies should always transmit the accurate Days' Supply of the quantity dispensed. The On-Line Adjudication Processing system will communicate the allowable number of days per the Member's Plan limitation, up to ninety (90) day supply when allowed by the Payors' Plan Specifications.

Participating Pharmacies shall have no right to dispense quantities of Covered Products to Members in excess of Days' Supply as limited by the applicable Plan Specifications or an executed applicable network addendum to the Agreement, except as permitted by applicable Law. Should the Days' Supply submitted exceed the Member's Plan limitation, the message 9G- "Quantity dispensed exceeds maximum allowed" will display.

If exact directions are not provided by the Practitioner (e.g., "as directed" or "prn"), the pharmacist must contact the Practitioner to obtain mathematically useful directions so an accurate Days' Supply can be calculated and submitted. The Practitioner's verbal indications must be documented on the original prescription in accordance with applicable legislation. Documentation should include changes to directions, authorizing agent, date, time, and pharmacist's initials.

Refills

Pharmacies cannot push-bill or auto-refill prescriptions for Medicare or Medicaid Members without the Member consent or request or when prohibited by State Law as described in the Auto-Refill section. This also applies to prescriptions that are mailed to Members.

Refills must be specifically indicated by the Practitioner. Original orders or refill requests initiated by the pharmacy should not contain the default number of refills. Refills good for 5 fills, 6 months, 1 year, etc., unless otherwise stated, will not be accepted. The number of refills authorized must be initiated by the Practitioner.

Refill Limitations:

- DEA schedule = Ø: Original + 11 refills within 365 days from original prescription-written date (or as further limited per Federal/State regulations)
  Per Navitus policy, claims are not allowed to be refilled beyond 1 (one) year of the prescription-written date.
- DEA schedule = 2: No refills allowed
- DEA schedule = 3, 4, 5: Original + 5 refills within 185 days from the original date Rx was written (or per Federal/State regulations)

NDC# and Package Size

Pharmacies are obligated to submit claims using the lowest ingredient cost dosage form and lowest-cost package/size container available. When pharmacies submit a claim, they must submit the correct NDC for the medication dispensed to the Member.

Drugs labeled, "to be dispensed only in the original container or package," must be dispensed in the original packaging for plans that cover such drug products. All other packages, such as nitroglycerin

patches, are considered "breakable" and, as such, must be dispensed for the quantity prescribed.

Repackaged/Relabeled Products

Navitus allows original manufacturer NDCs only. Navitus does not allow submission of repackaged products and will reject any repackaged or relabeled NDC. Claims for repackaged and/or relabeled NDCs submitted to Navitus will be subject to full audit recovery.

Generic Substitution

Pharmacies should substitute a generically equivalent drug for the brand prescribed, unless the Practitioner writes on the prescription in his/her own handwriting, the words "Brand Necessary," "Brand Medically Necessary" or similar wording as required by Law.[67]

Navitus will follow the NCPDP standard designation for "Dispense as Written" (i.e., DAW 1) for electronic prescriptions. The Practitioner must indicate on the electronic prescription that DAW 1. In the "Notes to the Pharmacy," the Practitioner must type "Brand Medically Necessary" or similar wording, as required by Law, to indicate that the brand is to be dispensed. If the electronic prescription is received by the pharmacy with DAW 1, but without the corresponding message, the pharmacist must contact the Practitioner for a new prescription.

Handwritten prescriptions must include the words "Brand Medically Necessary" in the Practitioner's handwriting on the face of the prescription. Navitus does not allow pre-printed DAW notations. For telephoned prescriptions, the pharmacist should write "DAW" on the prescription and indicate whether it is Practitioner-originated or patient-originated.

Member Cost Sharing liability varies by each Payor's Plans Specifications. Some Payors allow the use of DAW codes while others do not. Pharmacies should rely on the On-Line Adjudication Processing system for plan details. Navitus monitors frequent submissions of DAW codes and trial adjudications. Use of DAW 1 is not allowed if it was not initiated by the Practitioner in the original prescription. Navitus considers such inappropriate use as Fraud, Waste and Abuse and the pharmacy may be subject to investigation, audit, or claims recovery.

Pharmacies are to use DAW 2 when a Member requests a Brand Drug. Any other DAW is unacceptable. Pharmacies must annotate the Member's request for a brand name in place of a generic on the hard copy prescription. Claims that do not include the appropriate annotation are subject to recovery.

Prescriptions with a DAW request must indicate the DAW code in the NCPDP field 408-D8 (Product Selection Code) on the submitted claim.

[67] 42 C.F.R. §447.331 and 22 T.A.C. §309.3

Dispense as Written (DAW) Codes

The table below indicates the DAW codes for claims submission. Codes may differ between Payor plans and can affect reimbursement.

DISPENSE AS WRITTEN (DAW)/PRODUCT SELECTION CODE (408-D8)	
DAW 0	No Product Selection Indicated (Substitution Allowed) • This is the field default value that is appropriately used for prescriptions for single source brand, co-branded/co-licensed, or generic products. • Use when dispensing a multi-source generic, even if the prescribing provider indicates the DAW code for the generic product but does not specify a manufacturer • Use when dispensing single-source brands (e.g., Invokana) because generic substitution is not possible
DAW 1	Substitution Not Allowed by Prescriber (Practitioner writes DISPENSE AS WRITTEN or BRAND MEDICALLY NECESSARY) • Use when the prescribing provider specifies the branded version of a drug on the hard-copy prescription or when instructed orally • If the Member requests a brand, and it is not a prescribing provider-initiated instruction, transmit the DAW 2 code. (See following instruction.)
DAW 2	Substitution Allowed-Patient Requested Product Dispensed (Member requested) • Use when the Member or the Member's representative requests a branded drug, even if the original prescription did not indicate "Dispense As Written"
DAW 5	Substitution Allowed-Brand Drug Dispensed as a Generic • Use when dispensing a brand as a generic • Claims submitted with DAW 5 will be reimbursed at the generic price
DAW 9	Substitution Allowed by Prescriber (Practitioner) but Plan Requests Brand • Appropriate when the Practitioner indicates product substitution is allowed, but the Member's Plan Formulary prefers brand to be dispensed. (This applies to certain plans only.)

Exclusions for Experimental and Investigational Services

Navitus will not allow coverage of the following drug therapies, medications, treatments, or formulations ("Products") in the absence of an approved clinical trial, where required by law, or where other coverage is explicitly available from a plan sponsor. Navitus will disallow payment of products used for purposes other than approved indications unless supported by nationally recognized studies or convention.

- Products which are not approved by the US Food and Drug Administration to be lawfully used or marketed for the intended purpose or modified in its intended form.

- Products which do not improve net health outcome or cannot be attained outside of a research setting
- Products which have not been determined to be safe and/or effective for a medical condition
- Products which are currently in clinical trials or studies where safety, dose, efficacy, or procedural accuracy has not yet been determined or is recommended for further study.
- Products which lack or have insufficient clinical evidence from well-sized and scoped medical or scientific studies or trials published through federal research institutes or agencies or peer-review journals.
- Products which are provided by a provider who does not demonstrate proficiency, safety, or clinical knowledge in the preparation, dispensing, or delivery of the product.
- Products which lack credible evidence to support the use when compared with standard drug therapies, medications, treatments, or formulations.

Compounded Prescription Drug

A compounded medication may be the best choice when a commercial product or a particular dosage form is not available. A compounded medication consists of two or more FDA-approved ingredients, one of which must be a Formulary federal legend drug. Ingredients are combined in the exact strength and dosage form tailored for a Member. Pharmacies are responsible for compounding approved ingredients that are of acceptable strength, quality and purity and with appropriate packaging and labeling, in accordance with USP and good compounding practices.

Navitus will reimburse for a compound drug if compounds are included in the Payor's covered benefit. Any drug used in a compound must follow the plan's Formulary as if each drug component was being dispensed individually. Please contact the appropriate call center found on the Member's card to confirm whether a Payor allows Compounded Prescription Drugs.

NDCs submitted for the compound must be the exact formulation of what is dispensed. If a compounded prescription ingredient is not approved by the FDA (e.g., Estriol), it is considered a non-covered product and will not be eligible for reimbursement; however, it must be submitted with the claim.

A compound worksheet or recipe is required (for audit purposes) with the prescription documentation and should include:

- name, strength, and dosage form of the compound
- names, quantities, NDCs and lot numbers of **all** ingredients included in compound
- date, time, and name of the person who compounded the medication
- prescription number of the compound
- beyond-use date of compound; determination for the beyond-use date may be requested

Compound drug labels must list all active ingredients and strengths. For example, "Magic Mouthwash" is not an acceptable compound name as it does not indicate the make up of the product. The label should also include the lot number (if one was provided) and the compound's expiration date.

Compound billings and worksheets must include every ingredient and the exact metric quantity of each ingredient.

Navitus uses the claim's compound and DUR segments to adjudicate a Compounded Prescription Drug.

- Use the Compound Code "02" (NCPDP field 406-D6) to submit a compound claim
  - Claims billed with a value "0" will reject with the NCPDP D.0 ***Reject Code 20: M/I Compound Code***.
- Navitus requires a compound claim to include the correct NDC for each ingredient (active and non-active) within the Compounded Prescription Drug. There must be a minimum of two NDCs and a maximum of 25 NDCs (NCDPD field 447-EC)
- The claim must include a qualifier of "03" (NDC) to be populated in NCPDP field 448-RE, followed by NCPDP field 489-TE (NDC's)
- Pharmacies must submit a final product quantity
- Pharmacies must submit the total ingredient cost
- Pharmacies must submit the claim online and follow the POS messages that pertain to the ingredient coverage. If a prior authorization (PA) is required, pharmacies should follow the POS messaging to obtain a PA. Pharmacies should not circumvent the PA process by altering the Days' Supply and maintaining the same quantity or by reducing the quantity and Days' Supply to achieve a paid claim.

If an NDC for a non-covered drug is submitted, the claim will be denied.

- If pharmacies are willing to accept non-payment for the ingredient, an "8" in the Clarification Code Field (420-DK located on the D.0 Claim Segment Field) should be submitted. That allows the claim to pay, and the pharmacy reimbursed for all drugs except the rejected medication(s).

Many Payors require prior authorization (PA) for compounds that exceed $200. For rejections, pharmacies should obtain a PA. If a compound includes a drug that requires PA under the Member's Plan, the PA must be approved before the compound is submitted.

Manual compound claims forms are available at www.navitus.com and the Appendix of this manual.. Pharmacies are to submit for reimbursement the appropriate Level of Effort Code based on the complexity of the Compounded Prescription Drug. The code is to be populated in the NCPDP Field 474-8E (Level of Effort-DUR segment). Compounded Prescription Drugs that are made in large batches and then divided and dispensed to multiple Members should not include a level of effort

code in excess of 11. Navitus will require complete batch records and will validate the accuracy of those records. Pharmacies that submit incorrect or excessive Level of Effort codes may be reviewed by Navitus' Audit Team or Special Investigation Unit (SIU) for FWA.

Code	Complexity	Examples	Reimbursement Amount
11	Lowest	Straightforward: Minimal amount of drug handling or storage to consider. (e.g., "Magic Mouthwash," and other combinations of manufactured dermatological creams/ointments)	$15.00
12	Low	Service involves limited amount of drug handling or storage to consider. (e.g., simple suspensions, dermatological preparations)	$25.00
13	Moderate	Service involves moderate amount of drug handling or storage to consider. (e.g., Omeprazole or Lansoprazole suspensions, pain creams in liposomal bases, troches, suppositories, capsules)	$35.00
14	High	Service involves multiple amounts of dose calculations/conversions, drug handling, or storage to consider. (e.g., compound drug hormone, topical pain creams containing controlled substances, chemotherapy preparations)	$50.00
15	Highest	Comprehensive: exceptional amount or complexity of dose calculations/conversions, drug handling or storage to consider (any sterile compound drug)	$75.00

Sample NCPDP fields for the submission a compound claim:

450-EF	COMPOUND DOSAGE FORM DESCRIPTION CODE
451-EG	COMPOUND DISPENSING UNIT FORM INDICATOR
452-EH	COMPOUND ROUTE OF ADMINISTRATION
447-EC	COMPOUND INGREDIENT COMPONENT COUNT
488-RE	COMPOUND PRODUCT ID QUALIFIER
489-TE	COMPOUND PRODUCT ID
448-ED	COMPOUND INGREDIENT QUANTITY

449-EE	COMPOUND INGREDIENT DRUG COST
49Ø-UE	COMPOUND INGREDIENT BASIS OF COST DETERMINATION
474-8E	DUR/PPS LEVEL OF EFFORT

Unacceptable Practices for Medications Billed as Compounded Prescription Drugs

Navitus considers the following practices to be unacceptable:

- Billing for NDCs other than those listed on the compound drug worksheet/recipe
- Billing a dosage form other than what is listed on the compound drug worksheet/recipe
- Billing for reduced quantities or Days' Supplies to circumvent the PA process
- Rolling back the price to stay under the prior authorization threshold.
- Billing reconstitutable medications for which water or alcohol is added as the final ingredient prior to dispensing
- Billing for a compound that has a commercially available equivalent product available
- Billing Compound Prescription Drug claims for Members where there is no doctor-patient relationship. It is required for a Member and a Prescriber to have a professional relationship that can be evidenced by encounter or medical data.
- Billing a compound drug name that does not include the active ingredients and strengths
- Incomplete or missing worksheet/recipes
- Prescriptions with tiered drug groups that have automatic substitution for alternative compounds
- Dispensing a large quantity to a Member, but submitting multiple refills in smaller quantities in short periods to circumvent a plan's quantity or dollar threshold
- Adding ingredients that are not prescribed
- Failure to follow POS messaging regarding rejected claims
- Omitting ingredients to get a claim to pay
- Billing ingredients as individual prescriptions and then compounding the product for the Member using those ingredients
- Manufacturing compound drugs in the absence of proper authority, certification or licensure from the pharmacy board or State

Coordination of Benefits (COB)

Navitus supports electronic COB, split billing, and secondary claims in accordance with NCPDP standards. The COB segment is required to submit secondary claims. COB values one (1) through eight (8) are supported and will drive the claim if secondary adjudication applies.

Claims denied by the primary carrier should be submitted with the NCPDP standard reject code identified on the COB segment. If a reject message indicates the carrier does not accept secondary coverage, notify the Member. Participating Pharmacies are required to accurately coordinate benefits for Members and submit both primary and secondary claims, as directed by the Member and in

compliance with applicable Laws and regulations. COB is required under Medicare Part D[68,69] (see) and State Medicaid. Many of Navitus' commercial plans coordinate benefits for their Members.

COB claims can be submitted electronically up to 90 days from date of service.

Timely Filing Limits

Point-of-sale claims are usually submitted when a medication is dispensed. On occasion, there can be a mitigating reason that requires a claim to be submitted after it is dispensed. However, transmitting a claim using the current date for a past service date is a violation of this manual and could result in an audit error.

The timely filing limit from the date of service is 90 days for all initial claims. Claims that exceed the prescribed timely filing limit will deny with NCPDP Error 81, "Claim Too Old by x days." The exception is for claims for Members who have been certified with retroactive Medicaid eligibility. These claims may be submitted up to 90 days after the certification date of retroactive eligibility, for dates of service during this retroactive eligibility period.

Federal/State Disaster

When a Federal or State disaster is declared, Navitus' clients have the option to temporarily remove the "refill too soon" (RTS) edit. When a disaster is declared and the RTS edit is relaxed, affected pharmacies attempting to fill a medication sooner than allowed, may or may not receive a rejected claim. For Medicare claims, upon receipt of the rejection "Refill Too Soon," pharmacies can resubmit the claim by entering '13' in the Submission Clarification Code (SCC) Field. (DK620).

To ensure compliance, Navitus will conduct monitoring and oversight on the usage of SCC '13' on submitted claims. This includes the number of times a claim is filled for a Member during the time limit of the disaster declaration. For commercial and exchange Members the usage of SCC '13' is limited to once every 180 days. Outreach to Participating Pharmacies may occur when outliers are identified that raise potential concerns.
Participating Pharmacies also have a responsibility to evaluate appropriate dispensing to members and to report members to Navitus where such members appear to be seeking excessive refills in quantities that may be wasteful or abusive.
Pharmacies are responsible for being aware of disaster declarations, public health emergencies or other alerts that remove restrictions on claims processing where members may exploit such restriction removal for abuse or excessive refills.
Navitus expects pharmacies to monitor and inquire with Members' prescription filling behaviors.

[68] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter14.pdf
[69] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter14.pdf

Claims—Remittance

Navitus shall remit to Participating Pharmacy funds for eligible claims requesting payment of Covered Pharmacy Services in accordance with Exhibit A (Participating Pharmacy Reimbursement) to this addendum and each other pricing addendum selected by Participating Pharmacy in connection with this addendum, less all Cost Sharing Amounts. Participating Pharmacy agrees and reaffirms that under the Participating Pharmacy Agreement and this addendum, Navitus is not responsible or liable for the funding of claims and is not a guarantor or insurer for the funding for claims. Payment shall be remitted from funds received from applicable Payors to Participating Pharmacy.

Electronic Fund Transfer (EFT) and 835 Remittances

Navitus offers pharmacies the option to receive payments via automated clearing house (ACH) and remittances through electronic ASC X12 5010 835 (accessible through a file transfer protocol [FTP] server). For participating pharmacies to receive ACH payments, they must complete:

- an Electronic Fund Transfer (EFT) form and a
- 835 request form

Forms may be found at www.navitus.com. Send completed forms to Navitus.

- Fax: 608-298-5877
- Email: remittanceinquiry@navitus.com
- Mail: Navitus Health Solutions, Attn: Pharmacy Networks
  1025 W Navitus Drive, Appleton WI 54913

Pharmacies that want to continue to receive paper checks, but prefer an electronic remittance through the secured FTP server, need to fill out the 835 form or go to www.navitus.com.

Please allow 21 business days for setup as Navitus places test files on the FTP server to assure a smooth transition for pharmacies.

After the initial set-up, Participating Pharmacies are responsible to obtain the 835 files from the FTP server within 14 business days. Files that are not retrieved within 14 business days will automatically delete from the server. Navitus reserves the right to charge an additional fee to recreate an 835 file or create a CD.

Rejected claims denied through the online adjudication system do not appear on the Remittance Advice.

Payment Cycle

Navitus shall pay each funded clean claim via paper or electronic draft, as applicable, submitted by Participating Pharmacy, within 14 days of the date on which an electronic claim is received and within 30 days of the date on which non-electronically submitted claims are received in accordance with these terms and conditions of this addendum. In no event shall payment be required to be made hereunder by Navitus pursuant to claims received more than ninety (90) days from the date services are rendered, unless Participating Pharmacy notifies Navitus in writing within such period that a claim for such services has been presented to another Payor for payment. To the extent that a Payor does not issue, mail, or otherwise transmit payment for a clean claim within 14 days of the date on which an electronic claim is received and within 30 days of the date on which a non-electronically submitted claim is received, the Payor will pay interest to the Participating Pharmacy consistent with applicable law.

Navitus' standard pharmacy payment cycle is twice monthly unless an alternative is required by Federal or State Law.

- Date of fill, 1st through 15th: Clean Claims payable within 30 days
- Date of fill, 16th through last day of month: Clean Claims payable within 30 days

The pharmacy reimbursement cycle for Medicare Part D and Medicare Advantage corresponds with CMS' guidelines of no longer than 14 days**.**

Pricing/MAC Research Requests

Navitus produces a proprietary MAC list and corresponding unit costs. We utilize multiple sources of information to determine each product's unit cost on the Navitus MAC List. Sources include pharmacy acquisition costs, information from various wholesalers and retail pharmacy providers, publicly available State-reported average acquisition costs, publicly available national average drug acquisition cost (NADAC) information as published by CMS, along with other applicable data.
Navitus' pricing is passed-through, which means pharmacies are reimbursed the same as clients are invoiced for claims. Navitus routinely adjusts MAC prices in response to information received from its provider partners. The full MAC list and a list of recent price changes are available on the pharmacy portal at www.navitus.com.

Please email or fax the Navitus Pricing Research Request Form for any reimbursement questions and concerns. The form is available through the Navitus Pharmacy Help Desk or the Provider Portal on our website, www.navitus.com. See the Appendix for more information on how to access.

Please be sure to provide the following information:

- complete pharmacy identifying information
- complete claim information (or attach a copy of the claim if it includes key details)

- a copy of the wholesaler invoice that lists the net acquisition cost of the product or other proof of purchase price; required.
- a list of discounts and chargebacks to confirm true acquisition costs
- note the primary wholesaler in the comments section

We will respond:

- via phone or in writing within 15 days of receipt of request or in accordance with State rules.
- if the NDC is approved for adjusted pricing, the pharmacy can reprocess within seven business days and the effective date of the adjustment would be for the fill date indicated on the Pricing Research Request Form.

Navitus does NOT guarantee that all claims produce a positive margin. Navitus will evaluate the information provided. However, it is not obligated to adjust any claim or make changes to the pharmacy reimbursement or MAC list.

Claims—Prescription Utilization Program

Population Health Programs

- Designs and implements **evidence-based population health management programs** that seek to achieve the health and well-being of Members at the lowest net cost
- Identifies and provides **actionable information** to Members, Practitioners and clients to improve medication use
- Develops programs that **complement** clients' benefit philosophies and objectives
- Adheres to **nationally validated quality indicators**[70] related to medication use
  Provides **documented** and **auditable** clinical program outcomes
- Delivers a **comprehensive approach to managing high-cost specialty drugs** through a robust specialty program designed to provide the highest level of tailored Member care
- **Proactively monitors** pharmaceutical trends to identify and intervene on the factors driving drug spend

Formulary

Payors utilize a Formulary to support cost-containment and quality of care. Navitus works with Payors to help create formularies that meet the needs of Members. The Navitus Pharmacy and Therapeutics Committee supports and reviews all standard formularies.

Formularies are provided for reference for drug therapy selections. Participating Pharmacies are expected to cooperate, administer, and dispense medications in accordance with the Formulary compliance program implemented by Navitus.

If a non-Formulary drug is prescribed, pharmacies should make an effort to contact the Practitioner to ask if the prescription can be changed to a covered Formulary product.

Step Therapy

Step therapy is a safe and effective method to reduce the cost of treatment by ensuring a proven and cost-effective therapy is tried before progressing to more costly remedies. Step therapy requirements are automated at the point of sale and adjudicate if all requirements are met. Participating Pharmacies should refer to the Member's Formulary to determine if the prescribed drug is subject to step therapy protocol.

The criteria to determine a step therapy includes, but is not limited to:

- the first-line drug is recognized as safe and effective
- the first-line drug is significantly less expensive than the second-line agent
- the second-line drug does not offer a significant clinical advantage over the first-line product

[70] Such as STAR, HEDIS, and PQA

Prior Authorization (PA)

Prior authorization requires a Practitioner to receive pre-approval for coverage of select drugs under the terms of the Payor's pharmacy benefit plan. The purpose of the PA program is to:

- increase appropriate utilization of certain drugs
- promote the use of clinical guidelines
- actively manage the risk of using drugs with serious side effects
- positively influence the process of managing drug costs

If the following rejection messages are received, the Practitioner can request an exception to coverage form or PA form be faxed to them, or pharmacies can download the form from www.navitus.com > Pharmacies > Pharmacies Login.

- "70: Product/Service Not Covered Plan/Benefit Exclusion"
- "75: Prior Authorization Required"
- "608: Step Therapy, Alternate Drug Therapy Required Prior To Use Of Submitted Product Service ID"

To prevent delays, Navitus requires the most current PA form specific to the Member's plan. Correct PA forms and exceptions to coverage criteria can be obtained from Navitus' Customer Care (preferred method).

Please note the following:

- **Some PA forms specific to a Payor or line of business may not be available on this site**
- Some PA forms vary by lines of business as a result of differing clinical criteria.
- Use of the incorrect form may result in a delay of coverage determination.
- Use of expired or incorrect forms from third parties (e.g., CoverMyMeds®) may also result in a delay of coverage determination.

If pharmacies receive a reject 70, Product/Service Not Covered Plan/Benefit Exclusion:

1) Pharmacies can change to a Formulary product with prescriber approval, or
2) Pharmacies or Practitioners can initiate an exception to coverage process
    a. Contact Customer Care to begin the exception to coverage process
    b. Customer Care will provide the Navitus Exception to Coverage form to the Practitioner (including the information required for approval)
    c. Practitioner's signature and direct authorization on the form is required
        i. Proxy or agent signatures from the pharmacy on the Practitioner's behalf are not acceptable.
3) When a determination has been made, notification will go to the Member and Practitioner

If pharmacies receive a reject 75, Prior Authorization Required:

1) Pharmacies can change to an unrestricted Formulary product with prescriber approval, or
2) Pharmacies or Practitioners can initiate the prior authorization process
    a. Contact Customer Care to begin the PA process
    b. Customer Care will provide Navitus' PA form to the Practitioner
    c. Practitioner's signature and direct authorization on the form is required
        i. Proxy or agent signatures from the pharmacy on the Practitioner's behalf are not acceptable.
    d. When a determination has been made, notification will go to the Member and Practitioner
    e. Practitioners have the option to complete the PA request over the phone, but completing the PA form is preferred because the criterion for coverage is clearly indicated on the form

Navitus may apply a limitation of coverage based on Practitioner specialty, trial and failure or contraindication to Formulary alternatives, patient lab values, diagnoses, and any other Member-specific clinical data necessary to determine appropriateness.

Non-Urgent Prior Authorization Requests

- Practitioners or pharmacies request the PA form or access it through www.navitus.com
- Practitioners complete and fax requests to the number listed on the form
- Practitioners will be contacted if additional information is needed
- Decisions will be rendered within the timeframe indicated on the PA form upon receipt of complete information
- Decisions will be faxed to Practitioners and letters mailed to Members
- If complete information is not received within the required timeframe, requests will be denied

Urgent (Life-Threatening) Requests

- Practitioners can request or obtain the applicable PA form from www.navitus.com
- Practitioners should contact Navitus Customer Care with notification that an urgent request was submitted. Practitioners can also write URGENT on the PA form if the need for the request is because of a life-threatening situation
- Practitioners will be notified of a decision as expeditiously as possible, most often within 24 hours.

DUR Programs

Navitus requires Participating Pharmacies to conduct drug utilization reviews (DUR) at the point of sale, per OBRA 90[71]. Reviews should compare prescribed medications against previous drug histories for the following edits:

- Clinically significant drug-to-drug interactions
- Therapeutic duplication
- Drug-disease contraindication
- Drug allergy interactions
- Incorrect drug dosage or duration of drug treatment
- Clinical abuse/misuse

Upon identifying any clinically significant conditions, situation or items listed above, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescriber.

Navitus will conduct retrospective reviews that monitor Practitioners and Participating Pharmacies for outlier activities. Retrospective reviews will also determine whether services were delivered as prescribed and consistent with payment policies and procedures.

Concurrent Drug Utilization Review (CDUR)

Navitus' CDUR program consists of various levels of responses, depending upon the level of severity of the interaction being measured. Navitus' claims adjudication system reviews areas including but not limited to potential drug-drug interactions, dose checks (high/low, maximum/minimum), drug-sex interactions, drug-age interactions, duplicate therapy, late refill, morphine milligram equivalent (MME) and acetaminophen high dose.

Potential levels of interactions are absolute, major, moderate, or undetermined. Depending on the severity of the interaction, Navitus may return a DUR message.

Hard Rejects cannot be overridden and require a call to the appropriate call center. Participating Pharmacies should receive a phone number to call with the reject.

Soft Rejects can be overridden by the pharmacy by using the following fields and values.
To override a soft reject, the following fields, must be populated:

439-E4: Reason For Service Code
440-E5: Professional Service Code
441-E6: Result of Service Code

[71] Social Security Act §1927 (ssa.gov)

The fields are located in the DUR/PPS Segment of the NCPDP telecommunication standard transaction.

DUR/PPS Segment (please refer to the NCPDP telecommunication standard Payor sheet)

473-7E DUR/PPS CODE COUNTER
439-E4 REASON FOR SERVICE CODE
44Ø-E5 PROFESSIONAL SERVICE CODE
441-E6 RESULT OF SERVICE CODE
474-8E DUR/PPS LEVEL OF EFFORT
475-J9 DUR CO-AGENT ID QUALIFIER
476-H6 DUR CO-AGENT ID

Reason for Service Codes—The following codes will be accepted by Navitus:

Code	Description
AR	Adverse Drug Reaction – Indicates an adverse reaction by a Member to a drug.
AT	Additive Toxicity – Indicates a detection of drugs with similar side effects when used in combination, could exhibit a toxic potential that is greater than either agent by itself.
DD	Drug-Drug Interaction – Indicates drug combinations for which the net pharmacologic response may be different from the result expected when each drug is provided separately
DI	Drug Incompatibility – Indicates physical and chemical incompatibilities between two or more drugs.
ER	Overuse – Indicates the prescription refill is occurring before the Days' Supply of the previous fill would have been exhausted.
HC	High Cumulative – indicates high cumulative morphine milligram equivalent (MME) in current opioid claims
EX	Excessive Quantity – Indicates the quantity is excessive for the timeframe for which the dru is being prescribed.
HD	High Dose – Indicates drug doses that are above the standard dosing range.

Code	Description
ID	Ingredient Duplication – Indicates the simultaneous use of drug products that contain one or more identical generic chemical entity.
LR	Underuse – Indicates a prescription refill occurred after the Days' Supply of the previous fill should have been exhausted.
MX	Excessive Duration – Indicates regimens that are longer than the maximal limit of therapy for a drug product, based on the product's common uses.
PA	Drug-Age – Indicates age-dependent drug problems.
SC	Suboptimal Compliance – Indicates a professional service was provided to counsel the Member regarding the importance of adherence to the provided instructions and of consistent use of the prescribed product, including any ill effects anticipated as a result of non-compliance.
SX	Drug-Gender – Indicates the therapy is inappropriate or contraindicated in either males or females.
TD	Therapeutic Duplication – Indicates that a simultaneous use of different primary generic chemical entities with the same therapeutic effect was detected.

Professional Service Codes—Select Professional Service Codes from the NCPDP External Code List:

Code	Description
CC	Coordination of Care – Case management activities of a pharmacist related to the care delivered by multiple providers.
DE	Dosing evaluation/determination – Cognitive service whereby the pharmacist reviews and evaluates the appropriateness of a prescribed medication's dose, interval, frequency and/or formulation.
MA	Medication Administration - Code indicating an action of supplying medication to a patient through any of several routes-oral, topical, intravenous, intramuscular, intranasal, etc.
MØ	Prescriber consulted – Indicates prescriber communication related to the collection of information or clarification of a specific problem.

Code	Description
MR	Medication review – Indicates comprehensive review and evaluation of a patient's entire medication regime.
PH	Patient medication history – Code indicating the establishment of a medication history database on a patient to serve as the foundation for the ongoing maintenance of a medication profile.
PM	Patient monitoring – Indicates the evaluation of established therapy for the purpose of determining whether an existing therapeutic plan should be altered.
PO	Patient consulted – Code indicating patient communication related to collection of information or clarification of a specific problem.
TC	Payor/processor consulted – Code indicating communication by a pharmacist to a processor or Payor related to the care of the patient.
RØ	Pharmacist Consulted Other Source

Results of Service Codes—Select Result of Service Codes from the NCPDP External Code List**:**

Code	Description
1A	Filled As Is, False Positive – Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert) and determines the alert is incorrect for that prescription for that patient and fills the prescription as originally written.
1B	Filled Prescription As Is – Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert) and determines the alert is not relevant for that prescription for that patient and fills the prescription as originally written.
1C	Filled, With Different Dose– Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert) and fills the prescription with a different dose than was originally prescribed.
1D	Filled, With Different Directions – Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert) and fills the prescription with different directions than were originally prescribed.

Code	Description
1E	Filled, With Different Drug – Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert) and fills the prescription with a different drug than was originally prescribed.
1F	Filled, With Different Quantity – Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert) and fills the prescription with a different quantity than was originally prescribed.
1G	Filled, With Prescriber Approval – Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert) and fills the prescription after consulting with or obtaining approval from the prescriber.
1K	Filled with Different Dosage Form – Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert) and fills the prescription with a different dosage form than was originally prescribed.
2A	Prescription Not Filled – Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert) and determines that the prescription should not be filled as written.
2B	Not Filled, Directions Clarified - Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert), consults with the prescriber or using professional judgment, does not fill the prescription and counsels the patient as to the prescriber's instructions.
3A	Recommendation Accepted – Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert), recommends a more appropriate product or regimen then dispenses the alternative after consultation with the prescriber.
3B	Recommendation Not Accepted - Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert), recommends a more appropriate product or regimen but the prescriber does not concur.
3C	Discontinued Drug - Cognitive service involving the pharmacist's review of drug therapy that results in the removal of a medication from the therapeutic regimen.
3D	Regimen Changed - Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert), recommends a more appropriate regimen then dispenses the recommended medication(s) after consultation with the prescriber.

Code	Description
3E	Therapy Changed – Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert), recommends a more appropriate product or regimen then dispenses the alternative after consultation with the prescriber.
3G	Drug Therapy Unchanged - Cognitive service whereby the pharmacist reviews and evaluates a therapeutic issue (alert), consults with the prescriber or uses professional judgment and subsequently fills the prescription as originally written.
4B	Dispensed, Palliative Care
4C	Dispensed, Hospice
4D	Dispensed, Cancer Treatment

For specific edits, Navitus will accept:

DUR REJECT 88	REASON FOR SERVICE	PROFESSIONAL SERVICE CODE (any one of)	RESULT OF SERVICE CODE (any one of)
Drug-Drug Interactions	DD (drug-to-drug interaction)	DE, MØ, MA, MR, PØ, PH, RØ	1A,1B,1C,1D,1E,1F,1G,1K,2A,2B,3A,3B, 3C, 3D,3E,3G
	AR (adverse drug reaction)	MØ, PØ, PH, MR	1A,1B,1C,1D,1E,1F,1G,1K,2A,2B,3A,3B, 3C,3D,3E,3G
	AT (additive toxicity)	DE, MØ, MR, PØ, PH	1A,1B,1C,1D,1E,1F,1G,1K,2A,2B,3A,3B, 3C,3D,3E,3G
	DI (drug incompatibility)	DE, MØ, MR, PØ, PH	1A,1B,1C,1D,1E,1F,1G,1K,2A,2B,3A,3B, 3C,3D,3E,3G
High Cumulative (Morphine Equivalent Dose)	HC	CC, MO, MR, RO	1A,1B,1C,1D,1E,1F,1G,3A,3B,3D,3E,3G, 3H,4B,4C,4D
Dose Range	ER	CC, MO, TC	1A,1B,1C,1D,1E,1F,1G,1K,2A,2B,3A,3B, 3C,3D,3E,3G

Therapeutic Duplication	TD	DE, MØ, MR, PØ, PH	1A,1B,1C,1D,1E,1F,1G,1K,2A, 2B,3A,3B,3C,3D,3E,3G

Retrospective Drug Utilization Review (RDUR)

Navitus' RDUR programs focus on determining the appropriateness, necessity, quality, and reasonableness of the medications that were dispensed to a patient through claims review.

The execution of RDUR interventions enables us to retrospectively review Member profiles that may have an opportunity for cost containment or safety optimization. These clinical alerts, and their associated patient profiles, are aggregated by practitioner for the initiation of an intervention specifically designed to improve therapeutic outcomes, as well as safety and quality of Member care. Intervention communication options are tailored to achieve the best results and include communication with the Member, the Member's Practitioner, and pharmacist.

Cost-Focused Programs—Participation in these programs may vary by Payor.

Tablet Splitting (RxCents)

- Identifies Members using medications that are eligible to be split
- Tablet splitters are sent to Members
- Interventions are sent to Members and Practitioners

Dose Consolidation

- Screens profiles of Members on multiple-dose medications that can be safely administered in a single dose with the same clinical benefit
  (e.g., 2x20mg tablets = 1x40mg tablet)
- Interventions are sent to Members and Practitioners

Generic and Lower-Cost Rx Alternatives

- Screens Member profiles for drug regimens that have equally effective, lower cost, brand Formulary and/or generic alternatives available
- Interventions are sent to Members and Practitioners

Safety-Focused Programs—Participation in these programs is standard. Reviews for this program begin after four months of participation and are then reviewed every four months following.

Controlled Substance Monitoring (CSM)

- Multiple prescriptions for controlled medications (Schedule II, III, IV and V) from more than one provider and filled at more than one pharmacy during a pre-defined period
- Navitus' clinical staff reviews Member profiles

- Appropriate interventions with Member profiles sent to Practitioners

Expanded Fraud, Waste, & Abuse (FWA)

- Multiple prescriptions for drugs with high potential for abuse
    - Drug categories include muscle relaxants, migraine medications and other medications that have potential for overuse or abuse
- Navitus' clinical staff reviews Member profiles
- Appropriate interventions with Member profiles sent to Practitioners

Duplicate Therapy

- Identifies Members receiving multiple prescriptions with similar therapeutic purposes
- Ability to simplify Members' drug regimens may save Members money and lead to greater adherence
- Navitus' clinical staff reviews Member profiles
- Appropriate interventions with Member profiles sent to Practitioners

Triple Threat (part of our Enhanced Duplicate Therapy offering)

- Identifies Members concurrently receiving prescriptions for opioids, skeletal muscle relaxants and benzodiazepines/hypnotics in a month for multiple months during a pre-defined period
- Navitus' clinical staff reviews Member profiles
- Appropriate interventions with Member profiles sent to Practitioners

Multi-Practitioner and Multi-Prescription

- Prescriptions from multiple health care Practitioners or Members with multiple drug regimens
- Appropriate interventions with Member profiles sent to Practitioners
- Identifies Members exhibiting the greatest potential for optimizing medication therapy with respect to the number of providers or number of concomitant medications
- Improves coordination of care and Members' adherence to medication therapy
- Helps reduce adverse drug events and duplicate therapies

Morphine Milligram Equivalent (MME)

- Identifies Members who have been prescribed an average of 90 MME or greater per day by one or more physicians within a specific time frame
- Profiles sent to providers also list potentiator medications filled by member(s), which can prolong and/or intensify the effect of opioids, and can increase the risk of opioid overdose
- Navitus' clinical staff reviews Member profiles
- Appropriate interventions with Member profiles sent to Practitioners

Claims—Clinical Patient Management

Pharmaceutical Care Incentives (PCI)

The Pharmaceutical Care Incentives (PCI) Program is designed to compensate pharmacists for extra time spent counseling Members and providing training. Eligible services are described below. Participation in this program is determined by Navitus' clients and may be modified or discontinued at any time.

Qualifying Clinical Services:

Formulary Interchange
NDC Number: 99999-9999-32
Submit quantity of 1
Reimbursement: $4.00

Eligible for billing when changing a Member from a non-Formulary drug to a Formulary drug where prior authorization (PA) is not required. Practitioner contact and approval is required. Formulary alternatives are available on the pharmacy portal at www.Navitus.com or by calling Customer Care. A qualifying example includes:

- Contacting the Practitioner and receiving approval to change from a Tier 3 drug to a Tier 1 or 2 drug that does not require a PA

For Texas Medicaid, eligible for billing when changing a non-preferred drug to a preferred drug that does not require a PA. Practitioner contact and approval is required. The Texas Medicaid Drug Utilization Review Board makes recommendations for the preferred drug list (PDL) and clinical prior authorizations four times a year and the PDL is updated twice a year (July and January). Formulary alternatives are available by calling Customer Care or by visiting www.txvendordrug.com. A qualifying example includes:

- Contacting the Practitioner and receiving approval to change from Xerese (acyclovir/hydrocortisone) to acyclovir

Therapeutic Interchange
NDC Number: 99999-9999-33
Submit quantity of 1
Reimbursement: $12.00

Eligible for billing when changing a Member's prescription to a more cost-effective option or switching a drug that requires a PA to a therapeutically equivalent agent that does not require a PA. Practitioner contact and approval is required. Qualifying examples include:

- Contacting the Practitioner and receiving approval to change from Denavir to acyclovir ointment
- Changing the strength and dose of a medication to a configuration that achieves the same prescribed dose with a lesser quantity (e.g., changing sertraline 50mg 1 tab qd to sertraline 100mg tab ½ tab qd)
- Contacting the Practitioner to discontinue a medication the Member no longer requires (e.g., PPI 2 months after initiation)
- Contacting the Practitioner to discontinue a drug that causes the Member an adverse effect and/or obtaining authorization to replace it with a safer alternative (e.g., stopping Metformin in a renal impaired patient)

Change of Dose
NDC Number: 99999-9999-34
Submit quantity of 1
Reimbursement: $5.00

Eligible for billing when the prescribed dose is higher or lower than the recommended dose or the duration for use is insufficient or excessive. Requires a prescription change to be approved by the Practitioner. Do not submit if the Practitioner omits essential information for billing, such as the strength of medication when multiple strengths are available, as a call to the Practitioner would be needed anyway. Qualifying activities include:

- Contacting the Practitioner and receiving approval to lower the dose according to renal function
- Contacting the Practitioner and receiving approval to increase the dose when an optimal therapeutic effect is not yet attained (e.g., target dosing) *
- Contacting the Practitioner to discontinue a drug because of a contraindication in hepatic or renal dysfunction, in the presence of a severe-rated interacting medication or when the patient is already receiving a therapeutic equivalent

*DUR rejects indicating a preferred strength for a medication are not eligible for change-of-dose billing (e.g., changing from clindamycin 150mg 2 qd #10 to clindamycin 300mg 1 qd #5).

Patient Compliance Monitoring
NDC Number: 99999-9999-35
Submit quantity of 1
Reimbursement $10.00

Eligible for billing when a pharmacist addresses compliance with the Member for two specific situations:

1. Educating the Member post-pick-up on the importance of finishing a short-term therapy. A qualifying activity includes:

    - Follow-up telephone call to the Member 3-4 days after dispensing an acute antibiotic or oral corticosteroid prescription, to assess the efficacy and tolerability and emphasize adherence to treatment. Documentation of the phone call should include name of pharmacy person who called, and the date and duration of the call.

2. Educating the Member on the importance of taking maintenance medication regularly when less than a 70% compliance rate is determined by any one of the following approaches: Days' Supply dispensed (not to include today) / total days between the last two fills; Member regularly requests to fill prescriptions > 10 days early or later than expected; or the Member regularly asks for refills of a medication for because it was lost or stolen. Notification to the Practitioner is required. Qualifying activities include:

    - Identifying and correcting reasons for late fills and communicating this with the Practitioner
    - Assessing and implementing a medication-organization plan that may or may not include a pill organizer, unit dose packaging or other adherence enhancing tools (the specific tool is not reimbursable). Communication of the adherence plan to the Practitioner is necessary.
        - This can be billed only once when the program is implemented. Do not bill with each fill.
        - Navitus does not reimburse for time spent setting up cycle med boxes.
    - Assessment, identification and addressing specific adherence barriers and approaches to overcome barriers. Barriers can include cost (switching drug to a lower-cost alternative), refill reminders, transportation issues (mail order or delivery services) and recruiting a reliable and willing caregiver to assist in the adherence plan.

Qualifying Training Services

Glucose Monitors
NDC Number: 99999-9999-36
Submit number of minutes (up to 30) as the quantity
Reimbursement: $1 per minute, up to 30 minutes
Limits: 1 billing of up to 30 minutes per member, per year

Inhalers and/or Peak Flow Meter
NDC Number: 99999-9999-37
Submit number of minutes (up to 10) as the quantity
Reimbursement: $1 per minute, up to 10 minutes
Limits: 1 billing of up to 10 minutes per member, every 6 months

Blood Pressure Monitor
NDC Number: 99999-9999-38
Submit number of minutes (up to 15) as the quantity
Reimbursement: $1 per minute, up to 15 minutes
Limits: 1 billing of up to 15 minutes per member, per year

Nasal Inhalers
NDC Number: 99999-9999-39
Submit number of minutes (up to 5) as the quantity
Reimbursement: $1 per minute, up to 5 minutes
Limits: 1 billing of up to 10 minutes per member, every 6 months

Insulin Training
NDC Number: 99999999948
Submit number of minutes (up to 20) as the quantity
Reimbursement: $1 per minute, up to 20 minutes
Limits: 1 billing of up to 20 minutes per member, every 3 months

Submitting Pharmaceutical Care Incentive (PCI) Claims:

General Information
PCI claims are submitted online utilizing the claims adjudication system. Please fill out the Pharmacy Care Incentives Documentation Form and use as guidance when billing.

The form includes the following fields:

- Member Name: Submit a claim under the Member for whom the intervention was performed

- Indicate the Service Provided by checking the box next to the service
- NDC Number: Use the NDC that corresponds to the intervention performed (see Reference Chart)
- Rx#'s from all Prescriptions: In most cases, this would include the Rx# of the original product prescribed and the Rx# of the product dispensed.
- Practitioner Name: If the prescription was changed, submit the Practitioner who authorized the change, but include both Practitioner's names on the documentation form.
    - Patient Compliance Monitoring- submit that the Practitioner was notified of the compliance issue
    - Patient Training- submit the name of the Practitioner who authorized the prescription
- Description of Change (for clinical services): Include a brief explanation of the change. Example: from Lyrica to Gabapentin
- Training Time in Minutes (for Member training): Limits apply. See Qualifying Training Services section for time limits.
- Date of Intervention or Care: The date the clinical service or training was provided to the Member. Reminder: PCI billing must be completed at the time the intervention was performed, not the date the prescription was filled.
- Patient Signature: A signature is required for all training billings and preferred for clinical services. Compliance monitoring that is completed via phone should include the name of pharmacy person spoken with and the date and duration of the call.

A Member may undergo more than one intervention at the point of service, such as multiple interventions in the same category or interventions from multiple categories. An intervention NDC can be billed only once per Rx number (e.g., compliance monitoring cannot be billed with each fill). We suggest that pharmacies mark or indicate the original prescription to reflect that it underwent a pharmacist intervention.

Payment to the pharmacy for PCI will be included in the normal pharmacy payment cycle. Navitus reserves the right to audit or request documentation of Practitioner contact and/or authorization. Participation in this program may vary by Navitus client. Reimbursement rates are subject to change or cancellation.

Participation in the following programs is determined by Navitus' clients and may be modified or discontinued at any time.

Medication Therapy Management (MTM)

Navitus promotes safe drug use through its MTM program. CMS regulations require an MTM program offering for Medicare Part D Members. Medication Therapy Management Program (MTMP) services are provided to Medicare Part D Members on behalf of Payors. The MTMP is designed to include an offer for a person-to-person Comprehensive Medication Review (CMR) for all qualifying

Members, as well as targeted outreach to Members and Practitioners based on pre-determined intervention opportunities. Inclusion of this program is determined by each Medicare Payor contracted with Navitus. MTM services are not a fee-for-service option for Participating Pharmacies

Navitus reserves the right to change, modify or terminate this benefit.

The purpose of the program is to improve therapy outcomes for Medicare Part D Members who have multiple chronic diseases and are at risk for medication-related problems by:

- improving participant knowledge
- improving medication adherence
- detecting and reducing adverse drug events
- monitoring and reducing patterns of overuse and underuse
- increasing adherence to national consensus treatment guidelines
- decreasing medication costs

The targeted approach of the MTMP is to review prescription claims to qualify Members and identify intervention opportunities. The MTMP team turns these identified opportunities into therapeutic interventions through a combination of mailings, faxes and personalized phone calls to Members and Providers. With each targeted outreach to a Member, the team highlights the Member's opportunity to receive a CMR.

Pharmacy agrees to participate in one or more medication therapy management programs ("MTMPs") established by Navitus or its Payors[72] and at a rate to be agreed upon in writing. Participating Pharmacy further agrees subject to its professional judgment: (i) to take those measures reasonably necessary in connection with such MTMPs, to ensure Part D Drugs prescribed to targeted Medicare Members are appropriately used to optimize therapeutic outcomes through improved medication use; and (ii) to reduce the risk of adverse events, including adverse drug interactions for such Medicare Members.

Medication Synchronization Benefit

Check the Member's plan to verify coverage for this service.

Medication synchronization occurs when the pharmacist coordinates a Member's prescription refills so the Member can pick them up on a single day each month. This benefit results in Payor, Member, and pharmacy satisfaction. The Payor will experience improved overall health care costs and an engaged population, while the pharmacy can expect regular, dependable traffic to the store. The

[72] 42 CFR §423.153(d)

Member will see improved medication adherence and health and will enjoy the convenience of fewer trips to the pharmacy.
Pharmacy staff should check corporate entities or wholesalers to see if there is a medication synchronization software or tracking program already available. If a program is not available, pharmacies can search online for synchronization software offerings. After the software is installed, or alternatively, if a paper-and-pen option is used, the claims adjudication system will automatically prorate the Member's refills, enabling the pharmacy to cycle fill the medication regimen going forward.

Client-Specific Programs

340B

The 340B Program is a drug pricing program implemented under Section 340B of the Public Health Services Act,[73] as amended, and related guidance and notices issued by HRSA and OPA, under which manufacturers that sell covered outpatient drugs at prices that do not exceed a statutorily determined price to eligible healthcare organizations, clinics, drug programs, hospitals and other safety net providers who qualify as 340B covered entities "HRSA Covered Entities". Pharmacies should meet all applicable Federal and State Laws, regulations, guidance, and notices relating to the 340B Program

Participating Pharmacies who are providing 340B pharmacy services will perform the following:

- Dispense covered outpatient drugs to Members in accordance with all applicable Laws and regulations
- Perform drug utilization review
- Support each Covered Entity's Formulary
- Maintain Member profiles for each Covered Entity
- Provide medication therapy management and other clinical pharmacy services
- Counsel and advise each Covered Entity's Members in accordance with the rules, limitations, and privileges incident to the pharmacist-patient relationship
- Maintain and retain books, records and reports (whether in written or electronic form) required under 340B program requirements
- Agree that such books, records, and reports shall be available for examination, inspection or audit
- Establish, monitor and maintain an inventory and dispensing tracking system suitable to prevent diversion of covered outpatient drugs to non-Members

[73] 42 USC §256b

Member Eligibility and Dispensing

Navitus, on behalf of its Payor and Participating Pharmacies, will develop, implement, and maintain a system to verify Member eligibility under HRSA guidelines. Participating Pharmacies will dispense covered 340B outpatient drugs only in the following circumstances:

- Upon presentation of a prescription bearing the applicable HRSA Covered Entity's name, Member's name, a designation that the Member is a patient at the HRSA Covered Entity, and the signature of a Provider affiliated with the HRSA Covered Entity; or
- Upon receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by Law for a Member from a Provider who is affiliated with the HRSA Covered Entity and states that the prescription is for an HRSA Covered Entity's Member.
- Navitus will furnish Participating Pharmacies with or publish a list of; each covered entity's qualified health care Practitioners and will regularly update such lists.

Prohibition on Resale, Transfer or Duplicate Medicaid Discounts

Participating Pharmacies will implement and maintain written policies, procedures and safeguards to avoid drug diversion and duplication of discounts in connection with the 340B Program.

- A Participating Pharmacy will not dispense, sell, or otherwise transfer any covered outpatient drug or other drug purchased at 340B Program prices to an individual who is not a qualified patient under the 340B program and Member.
- A Participating Pharmacy will not use covered outpatient drugs purchased under the 340B Program to fill or to dispense Medicaid prescriptions unless the applicable HRSA Covered Entity, Participating Pharmacy, and the state Medicaid agency have established a written arrangement or protocol to prevent duplicate discounts.
- If the Participating Pharmacy determines that, there has been diversion or duplicate discounts in connection with the 340B Program, the pharmacy will notify Navitus immediately in writing and cooperate with Navitus and the affected HRSA Covered Entities to remedy the problem.
    - If a Participating Pharmacy is determined by Navitus to have violated the drug diversion prohibition, the pharmacy will immediately pay Navitus the amount of any discount at issue for the purpose of enabling the HRSA Covered Entity to reimburse the manufacturer for diverted products.
    - Navitus reserves the right to immediately terminate the pharmacy's participation in the 340B network.
- The Participating Pharmacy acknowledges and agrees that covered outpatient drugs are subject to specific pricing under applicable 340B Laws.
    - The Participating Pharmacy will not directly or indirectly negotiate, contract or agree with any pharmaceutical manufacturer or other person for the purpose of obtaining access/performance Rebates, discounts, financial incentives, price concessions or rebate arrangements with, and other direct or indirect remuneration, that are designed to, or

likely to, directly or indirectly influence or affect utilization or volume of covered outpatient drugs (together, "Rebates").
    - The Participating Pharmacy further agrees to cancel, as of the effective date, any existing Agreements or contracts with any pharmaceutical manufacturers or other persons or entities to the extent such Agreements or contracts are related to such Rebates in connection with a Member's drug utilization.
- If the Participating Pharmacy takes any action which violates the 340B Agreement, Navitus may terminate the Agreement immediately upon written notice to the Participating Pharmacy or take such other corrective or remedial action as warranted under the circumstances.

Ship To and Bill To Process

The Participating Pharmacy acknowledges and agrees that under the 340B Program, HRSA Covered Entities own all covered outpatient drugs and arrange with manufacturers or their representatives to be billed directly for such drugs. The covered outpatient drugs will be shipped directly to the pharmacy. The pharmacy will compare shipments received to the orders and inform Navitus, in writing, of discrepancies within five (5) business days of receipt of the covered outpatient drugs. As between the Participating Pharmacy and Navitus, Navitus and each Covered Entity will be responsible to make timely payments to manufacturers and their representatives for covered outpatient drugs delivered to the Participating Pharmacy.

Recordkeeping and Audits

Navitus and the Participating Pharmacy will identify the necessary procedures, processes, books, records and reports for Covered Entities to meet their ongoing responsibility to ensure billing compliance, adherence to applicable 340B Laws, and to establish mechanisms to ensure availability of compliance information for periodic independent audits and investigations. These records requirements will survive the expiration or termination of the 340B Agreement. The pharmacy is required to **identify detailed reporting/records: dispensing, prescription orders, receipts of drugs/results of reconciliations.**

Separate Records

- A Participating Pharmacy will maintain books, records and reports (whether in written or electronic form) related to its duties and obligations under the 340B Agreement for the period required by Federal and State Laws and regulations.
- Books, records, and reports will include, but not be limited to, prescription files, inventory turn reports, inventory and ordering and receipt records and the Participating Pharmacy's tracking system.
- The Participating Pharmacy will ensure that all pertinent reimbursement accounts and dispensing records maintained by the pharmacy will be accessible separately from the

Participating Pharmacy's operations and will be made available to Navitus, covered entities, HRSA, manufacturers and their respective representatives.

- The Participating Pharmacy agrees to cooperate with audits, examinations, or inspections in connection with the 340B Agreement or with any Covered Entity's compliance with 340B Laws and other applicable Laws that may be published.

Audits

- Participating Pharmacies will provide documentation upon request from Navitus, each HRSA Covered Entity, manufacturer, auditor and their respective representatives. Such documentation shall include but is not limited to all controls to avoid drug diversion and duplication of discounts.
- Navitus, Covered Entities, outside parties (e.g., HRSA, OPA, HHS and manufacturers), and their respective representatives will have the right to audit, examine and inspect the Participating Pharmacy's books, records, operations, policies, procedures, processes and reports that are related to the Participating Pharmacy's duties and obligations under the 340B Agreement, including, but not limited to, compliance with the 340B Laws' prohibitions related to drug resale or transfer and duplicate discounts.
- The Participating Pharmacy acknowledges and agrees to all requirements of 340B Laws pertaining to audits, including, but not limited to, HSRA guidance that audits follow standard business practices for audits, including audit trails and use of standard reports.
- Navitus, Covered Entities, manufacturers and their respective representatives will have the discretion to determine the methodology to be used to ensure compliance and obtain the necessary information.
- This provision will survive the expiration or termination of the 340B Agreement.

Certification of Data

- The Participating Pharmacy acknowledges that books, records, reports, data and information provided or made available by the Participating Pharmacy to Navitus, a Covered Entity, a manufacturer, OPA HRSA, HHS or generated or created by the Participating Pharmacy as a result of the provision of 340B pharmacy services to Members, will be used by Navitus and its covered entities for compliance with applicable 340B Laws.
- The Participating Pharmacy certifies, represents and warrants that such books, records, reports, data and information will be accurate, complete and truthful.
- The Participating Pharmacy agrees that an officer with the authority to bind the Participating Pharmacy, will upon request certify the accuracy, completeness and truthfulness of all such books, records, reports, data and information; and acknowledge that all such books, records, reports, data and information will be used by Navitus and Covered Entities for purposes of compliance with applicable 340B Laws.
- In the event the Participating Pharmacy identifies inaccurate, incomplete books, records, reports, data or information that is not truthful as having been provided to Navitus, Covered Entities, a manufacturer or its respective representatives, the Participating

Pharmacy will promptly notify Navitus, in writing, and will promptly provide Navitus corrected information and all related documentation.

Safety-Net Institution Pharmacies

Participating Pharmacies that are contracted with or owned by safety-net institutions that purchase outpatient drugs under the HRSA 340B Program must submit claim values per the NCPDP Telecommunication Standard guidance (e.g., submission clarification code and/or basis of cost determination) that identify use of 340B inventory for the dispensed Covered Products to Members.

Required Use of NCPDP Claim Submission Values

- The Participating Pharmacy acknowledges and agrees that Navitus is required to report all claims submitted for drugs purchased under the 340B Drug Pricing Program to Payors and as applicable state Medicaid agencies, as appropriate.
- Navitus requires a Participating Pharmacy that dispenses 340B inventory drug to a Member, to populate industry-developed values in the NCPDP Telecommunication Standard fields to identify claims for non-340B Covered Products from 340B purchased drugs.
- The Participating Pharmacy will submit the value "20" in the Submission Clarification field (420-DK) and the value "08" in the Basis of Cost Determination field (423-DN) for all qualifying 340B claims.

Contracted payors are additionally required to report to Medicaid agencies all paid claims submitted for Covered Products purchased under the 340B program.

- HRSA policies, state Medicaid agency policies, Navitus and MCO Payor policies prohibit Payors from collecting Rebates for 340B claims.
- The Participating Pharmacy is subject to continual monitoring and audits of its use of the required NCPDP fields.

90-Day at Retail

The benefit limit for quantities of Covered Products may vary per the plan's limitations. At a minimum, a 34-day supply will be covered without a specific quantity limitation. Some plans may include a limited Formulary that allows up to a 90-day supply of a Covered Product. Pharmacies can process a 90-day supply claim for a covered product by using the Days' Supply field. A response that includes an NCPDP Plan Limitations Exceeded (Reject 76) will indicate that the particular product does not qualify for a 90-day supply.

Mail Order

Navitus subcontracts with multiple vendors to offer a choice of vendors to clients. Our objective is to provide alternatives that best meet the Payor's needs based upon geographic Location, pricing and utilization of a transparent business model. Pharmacies must be contracted as mail order to participate with Navitus as a mail order pharmacy.
Mail order pharmacies may be in the Members' network, and, depending on plan design, will be either mandatory or voluntary. In both situations, Members are not to be charged fees, such as postage or handling, for obtaining Covered Products at mail order Participating Pharmacies. Pharmacies are to submit claims using Pharmacy Service Type "6" in the 147-U7 field of the claim submission. Maintenance of either a signature log or a record of shipment, including tracking numbers, will be required for audit purposes.

Specialty Pharmacy

A number of Navitus' Payor benefit plans include a mandatory specialty program that requires the use of certain specialty pharmacy providers to obtain specialty medications. Medications that need to go through the specialty program will reject with code "4W" and the message, "PM excludes; required through specialty pharmacy; please refer to the phone number Navitus returns at point of sale for medications that require the use of the Navitus specialty pharmacy."

Specialty drugs are higher-priced medications that require additional clinical management and oversight to ensure efficacy and appropriate use in certain therapeutic categories. Navitus contracts with specialty pharmacy providers to distribute and manage the medications. Payors solely elect to use the specialty provider(s) and include the mandatory specialty therapies in their benefit designs.

State Medicaid Regulations

For Managed Medicaid, refer to the "State Regulatory Requirements" and Navitus' Payor Sheets and Bulletins for Plan Specifications.

For Fee-for-Service Medicaid, refer to the state-specific website.

Vaccinations

A number of Navitus Payor benefit plans include vaccinations. Commonly offered vaccinations include influenza, pneumonia, and shingles. Pharmacies participating in the vaccination program can process claims for vaccinations. If the vaccine is not covered, the pharmacy will receive the message, "NDC not covered." Pharmacies should consult the Formulary for a listing of covered medications.

Monitoring And Auditing

Overview

As the prescription benefit manager (PBM) for various Payors, Navitus has an obligation to ensure all contracted services are provided. Compliance with the Participating Pharmacy Agreement (PPA) is required. Navitus will perform pharmacy monitoring and audit functions to ensure program integrity. Navitus reserves the right to audit, examine and inspect the performance of Participating Pharmacy, its Locations, and each Approved Delegation, on an on-going basis, in any manner that the Payors or Navitus deem appropriate for compliance with the Payors' obligations. Audited pharmacies are identified based on internal analysis, external information provided to Navitus or compliance calls to Navitus. Advance notice is provided to pharmacies, unless otherwise specified in the PPA, as required by applicable State/Federal Law or if suspected fraud has been identified.

WHEN FRAUD IS SUSPECTED, NOTICE BY NAVITUS TO THE PHARMACY IS NOT REQUIRED!

Navitus' monitoring and audit activity will be in the form of pre-payment monitoring review, desk, on-site, invoice, correspondence or special investigation. Navitus will follow required audit rules for states with specific pharmacy auditing regulations. At Navitus' election, Participating Pharmacy shall provide Navitus with all Documents or copies thereof related to the provision of such Covered Pharmacy Services and/or certifications of Participating Pharmacy's compliance with the requirements of these terms. The rights specifically reserved for Navitus, and its Payors shall not relieve Participating Pharmacy from its duties or obligations under these terms.

Investigations, monitoring, and auditing activity can commence in accordance with the PPA at any time and audits can extend within one (1) year of the PPA termination. Failure to comply with an investigation, inquiry, audit or monitoring may result in recoveries and/or termination from the network. Pharmacies will receive written results following an audit.

Some audit considerations include, but are not limited to, the following errors:

- missing or incomplete signature logs
- dispensing an incorrect drug
- billing the wrong Member
- claims paid during Medicare Part D Transition
- missing hard copy
- claims submitted with Long-Term Care Submission Clarification Codes
- pharmacy use of pre-printed orders
- missing the compound drug worksheet/recipe
- using a DAW code incorrectly
- over/under billing quantities

- calculating the Days' Supply incorrectly
- billing the incorrect practitioner
- using an NCPDP/NPI number inappropriately
- dispensing unauthorized, early, or excessive refills
- improper documentation of authorized changes to the order
- pharmacy purchasing invoices that do not correspond with the NDCs of submitted claims for reimbursement
- expired or absent pharmacy credentials (licensures, insurance, etc.)
- pharmacy inventory discrepancies and or deficiencies
- Inappropriate relationships/affiliations with drug manufacturers
- excessive claim testing (Total final paid claims is less than 50% of total submitted claims)
- CMS AICE score over 800
- significant volume of services for members who are geographically distant
- dominant volume of prescriptions is for controlled substances or other medications associated with Fraud, Waste and Abuse

With the large volume of prescriptions processed every day, we realize human errors occur. Navitus recognizes that its Participating Pharmacies do an outstanding job of providing pharmacy services to Navitus Members.

Pre-payment Monitoring Claim Review

Adjudicated claims are run through designated algorithms. The algorithms score or "flag" the claims with suspicious attributes and/or inappropriately submitted claims.

Provider Services will contact (phone, fax, or email) pharmacies that show discrepancies to request review of the submitted claims.

Provider Services will work with pharmacies to educate and correct claims prior to payment processing. The pre-payment claims review does not stop the claim; therefore, there is not a disruption at the point of service (POS). The pre-payment review algorithms reflect frequent typing errors (input errors) by pharmacists or pharmacy technicians that appear on approved claims.

Desk Audits

A desk audit is a retrospective audit of adjudicated claims. Navitus will send a letter to the applicable pharmacy that requests copies of prescriptions and signature logs to be emailed, faxed, or mailed to Navitus within twenty (20) calendar days. If documentation is not received within twenty (20) days, a second notification will be sent, and the pharmacy will have an additional ten (10) calendar days to submit the documentation.

Upon review of the claims, a letter will be sent to the pharmacy with preliminary audit results. At that time, the pharmacy will be allotted thirty (30) calendar days to appeal the results. Appeals must be in writing. Acceptable appeal documentation can include Practitioner notes, Practitioner letters, written and/or electronic documentation of changes made to original hard copies with dates specified, or other items that support the claims in question. An optional form can be found in the Appendix and on the pharmacy provider web portal. Appeals will not be accepted after the thirty (30) day appeal period has passed. Final audit results will be faxed or mailed to the pharmacy after the appeal window closes and will include the dollar amounts of any financial recovery. No further appeals will be accepted once the final letter is issued unless specifically allowed by state law. Any appeals to the final letter will follow the same appeal process as that of the preliminary audit results.
(Audit requests on behalf of CMS for Acumen or PDE validation may have different timelines and document requirements. Specific information will be provided in audit notification.)

On-Site or Virtual Audits

Pharmacies selected for an on-site or virtual audit will receive notification thirty (30) days prior to the audit, or as specified in the Participating Pharmacy Agreement, required by applicable State/Federal Law or if suspected fraud has been identified.

The notification will inform the pharmacy of:

- date and time of the audit (if in person)
- auditor's photo (if in person)
- pharmacy records required for the audit (masked list of prescription numbers, signature logs, invoices, etc.)

On-site and virtual audits will be conducted during the pharmacy's regular business hours. For in-person audits, an auditor will visit the pharmacy to review its documentation in support of the claims submitted to Navitus. The auditor will review whether the pharmacy is in compliance through verification of Licenses, certifications, procedures and through reference to specific sections of the Provider Agreement and applicable rules, laws, and regulations.

Pharmacy staff will need to retrieve documentation. Audit documentation, including prescriptions and supporting documentation, may be copied/scanned by the auditor as permitted under HIPAA for operations and payment.

Following an on-site audit, the auditor will provide general feedback as to what was observed during the audit. Pharmacies will receive preliminary findings within fourteen (14) business days following the audit. Information on how to appeal the results of the audit will also be supplied.

For virtual audits, the auditor will review the requested documents in support of the claims submitted to Navitus and contact the pharmacy via phone or video call to review and findings. Pharmacies will

receive a letter including preliminary findings within fourteen (14) business days following the virtual interview and discussion. Information on how to appeal the preliminary findings will also be provided during the interview and included in the preliminary results letter.

Appeals

For onsite, virtual and desk audits, pharmacies will have thirty (30) calendar days from the date on the Preliminary Results letter to review the claim(s) in question and contest the results by supplying supporting documentation. Appeals to the final results letter are only considered if appeal is specifically allowed by state law. All Appeals must be submitted in writing. Please go to www.navitus.com for the appeal form. Multiple appeals on the same claim will not be considered.

Practitioner statements will be accepted only on the Practitioner's letterhead or the physician verification form in the appendix and should include:

- Practitioner's address and telephone number
- Member's full name and date of birth
- drug name and strength
- date written and method of transmission (origin)
- specific directions (include original and clarified directions)
- diagnosis (ICD-10), if required for claim payment
- quantity and refills authorized
- Practitioner's signature, date, and stamp (if available)
    - Telephone prescriptions are not acceptable as post-audit documentation.
    - Statements prepared by the pharmacy for a Practitioner to sign will not be accepted.

Member statements may be considered and should include:

- Member's address and telephone number
- drug name
- prescription number
- date of service
- Member's signature and date

The auditor will review the appeal and supporting documentation. The pharmacy will be notified of the final audit results after the appeal window is closed. Appeals will not be accepted after thirty (30) day appeal period has passed.

Audit Recoveries

Recoveries may be necessitated by claim errors that result from poor documentation or filing procedures. Premature destruction, incomplete records, clerical errors, or missing records will not be accepted as reasons for incomplete documentation. All unsubstantiated claims are subject to full recovery as a Navitus Overpayment. Audit recoveries can be handled by:

- offsetting the audit recovery amount from the pharmacy's next remittance

- requesting the pharmacy to reverse and reprocess the claim, if the claim is less than 90 days old
- collection request

Contact the Navitus Audit Department at 920-221-4100 with questions.

Audit Guidelines

Prescription Hard Copies—Requirements for a valid prescription:

- Member's full name and date of birth
- drug name and strength
- date written
- specific quantity to dispense
- specific directions that are mathematically useful to calculate day supply
- DAW, if applicable
- refills authorized, if applicable
- Practitioner's DEA for controlled prescriptions
- Practitioner's signature
- name of other authorizing Practitioner, if different from named Practitioner such as a supervising physician.

Changes made to the original order must be documented in accordance with State and Federal Laws. At a minimum, documentation should include date, time, name of the agent authorizing the change and the pharmacist's initials. "Per MD" is not acceptable documentation.

Signature Logs—At a minimum, a signature log should include the Rx number, date filled, date picked up or delivered and signature of the Member, caregiver or authorized representative who picked up the prescription. The pharmacy should ensure its process incorporates all state requirements.

- **Reminder: Pharmacies are required to complete reversals of the Prescription Drug claim within the same payment cycle as the submission or no later than fourteen (14) calendar days after the claim was adjudicated where prescriptions have not been delivered to or picked up by Member.

Use as Directed—Navitus' standard requires the pharmacy to obtain specific direction that are mathematically useful in calculating day supply for use. Prescriptions should include detailed directions to ensure the accurate calculation of Days' Supply. If directions are unclear, the pharmacy must call the Practitioner, verify the directions, and Document the specific directions on the hard-copy prescription. The pharmacy must also note the date and time the information was received, the agent that clarified the order, and the pharmacist's initials. For medications that fluctuate in dosage, the pharmacy must verify a maximum or "up to" daily dose. Prescriptions for topical agents must describe

the affected area and note the information on the hard copy. "Apply to affected area" will not be accepted.

Quantity/Days' Supply—Pharmacies should submit the exact quantity authorized by the Practitioner in correlation with the correct Days' Supply. If the claim rejects, it should be re-adjudicated with a quantity and Days' Supply supported by the Member's benefit plan. Click here for information on Days' Supply.

Dispense as Written—For prescriptions submitted with a DAW other than "0", the reason for the selection code must be documented on the hard-copy prescription and in compliance with applicable Laws, rules and regulations. Click here for information on selection codes for DAW.

Ophthalmic/Otic Solutions/Suspensions—Navitus calculates ophthalmic and otic medications using 16 drops per ML, unless otherwise indicated by the manufacturer. Claims should be submitted based on the 16 drops per ML or manufacturer guidelines for the proper calculation of Days' Supply.

Origin Code—All prescriptions must be submitted with an accurate and valid origin code in field 419-DJ.

- 1 = written: Prescription obtained via paper
- 2 = telephone: Prescription obtained via oral instructions or interactive voice response using a phone
- 3 = electronic: Prescription obtained via SCRIPT or HL7 standard transactions
- 4 = facsimile: Prescription obtained via transmission using a fax machine
- 5 = pharmacy: Any situation where a new Rx number is assigned from an existing valid prescription

Practitioner Identifiers—Navitus requires Participating Pharmacies to submit the correct and valid NPI of the prescribing Practitioner for each claim. Organizational NPI numbers will not be accepted.

- If applicable, the pharmacy must submit the correct and valid prescribing Practitioner DEA number.

NAVITUS HELP CHARTS

OPHTHALMICS—16 drops (gtts) per ML
(unless otherwise specified by the manufacturer)
Be sure to consider product expiration when calculating the Days' Supply.

Total Gtts/Days	Days' Supply for Quantity MLs Dispensed				
	2.5 ML	5 ML	10 ML	15 ML	20 ML
1	40	80			
2	20	40	80		
3	13	27	53	80	
4	10	20	40	60	80
6	7	13	27	40	53
8	5	10	20	30	40

INHALERS

Inhalers billed by doses per unit	Available strengths	Quantity to bill	Doses per unit
Advair Diskus (fluticasone-salmeterol) *	100/50, 250/50, 500/50	60	60
Anoro Ellipta (umeclidinium-vilanterol)		60	30
Arnuity Ellipta (fluticasone furoate)	100, 200	30	30
Breo Ellipta (fluticasone furoate-vilanterol)	50/25, 100/25, 200/25	60	30
Flovent Diskus (fluticasone propionate)	50, 100, 250	60	60
Incruse Ellipta (umeclidinium bromide)	62.5	30	30
Serevent Diskus (salmeterol xinafoate)	50	60	60
Spiriva Handihaler (tiotropium bromide mono)	18	30, 90	30, 90
Trelegy Ellipta (fluticasone-umeclidinium-vilanterol)		60	30
Wixela Inhub (fluticasone-salmeterol) *	100/50, 250/50, 500/50	60	60
Inhalers billed as quantity of units	**Available strengths**	**Quantity to bill**	**Doses per unit**
Airduo Respiclick (fluticasone-salmeterol) *	55-14, 113-14, 232-14	1	60

ArmonAir RespiClick 55mcg (fluticasone propionate)	55, 113, 232	1	60
Asmanex 110mcg (mometasone furoate)		1	30
Asmanex 220mcg (mometasone furoate)		1	30, 60, 120
Lonhala Magn 25mcg (glycopyrrolate)	Starter kit and refill kit	1	60
Proair Respiclick (albuterol sulfate)		1	200
Pulmicort 180mcg (budesonide)		1	120
Pulmicort 90mcg (budesonide)		1	60
Tudorza (aclindinium bromide)		1	30 & 60

Inhalers billed by weight (grams)	**Available strengths**	**Quantity to bill**	**Doses per unit**
Advair HFA (fluticasone-salmeterol)	45/21, 115/21, 230/21	12	120
Aerospan HFA (flunisolide HFA)		8.9	120
Airsupra (albuterol sulfate – budesonide)		10.7	120
Alvesco (ciclesonide)	80, 160	6.1	60
Asmanex HFA (mometasone furoate)	100, 200	13	120
Atrovent HFA (ipratropium bromide HFA)		12.9	200
Breyna (budesonide - formoterol fumarate)	80/4.5, 160/4.5	10.3	120
Breztri Aerosphere (budesonide, glycopyrrolate and formoterol fumarate)		10.7	120
Combivent Respimat (ipratropium-albuterol)		4	120
Dulera (memetasone furoate-formoterol fumarate)	100/5, 200/5	13	120
Flovent HFA (fluticasone propionate HFA)	110, 220	12	120
Flovent HFA 44 (fluticasone propionate HFA)		10.6	120
Proair HFA (albuterol sulfate) *		8.5	200
Proventil HFA (albuterol sulfate) *		6.7	200
Qvar (beclomethasone diprop)	40, 80	8.7	120
Qvar Redihaler (beclomethasone diprop HFA)	40, 80	10.6	120
Spiriva (tiotropium bromide mono)		4	60
Stiolto Respimat (tiotropium bromide-olodaterol)		4	30
Symbicort (budesonide-formoterol fumarate)*	80, 160	10.2	120
Ventolin HFA (albuterol sulfate) *		18	200
Xopenex HFA (levalbuterol tartrate) *		15	200

*Generic available. Check Formulary for coverage.

INSULIN PRODUCTS

Be sure to consider product expiration when calculating the Days' Supply (e.g., Humalog; 28 days once opened)

Navitus prefers the splitting the cartons, but it is not required. Pharmacies should always calculate and bill the true day supply and may reduce the day supply per the plan limitations if a *7X-Day Supply Exceeds plan limitation* rejection is received.

NOTE: The pharmacy must refill according to the true day supply and not the billed day supply.

Total Units/Days	Days' Supply for Quantity MLs Dispensed (100 units/ML)								
	10 ML	15 ML	20 ML	30 ML	40 ML	45 ML	50 ML	60 ML	90 ML
20	50								
30	33	50							
40	25	38	50						
60	17	25	33	50					
80	13	19	25	50	50				
100	10	15	20	30	40	45	50		
120				25	33	38	42	50	
140				25	29	32	36	43	
160				19	25	38	31	38	56
200				15	20	23	25	30	45

DIABETIC TESTING STRIPS

Total Tests/Days	Days' Supply for Quantity of Strips Dispensed							
	50/51	100/102	150/153	200/204	250/255	300/306	400/408	900/918
2	25	50	75	100				
4	13	25	38	50	63	75	100	
6			25	34	42	50	68	
8				25	31	38	50	
10					25	30	40	90

NASAL SPRAYS

Total Sprays/Days	Days' Supply for Sprays per Container	
	120 Sprays	200 Sprays
2	60	100
4	30	50
8	15	25

UNUSUAL SUBMISSION REQUIREMENTS

Drug Name	Unusual Features	Common Dosing	Qty to Submit	Days' Supply
Elimite®/Eurax® (permethrin)	Can be ordered for all Members of a family on one prescription blank, in accordance with State Law	One treatment course per person	Submit a separate claim for each family member, unless otherwise allowed by State Law	Elimite: 1 Eurax: 2
Enbrel® Prefilled Syringe 50mg (etanercept)	One package with four single-dose syringes	Varies	3.92	Varies according to dosing
Lariam® (mefloquine)	Prophylaxis dosage: one tablet per week	Four tablets per month	4	28
Prevpac® (lansoprazole, amoxicillin & clarithromycin)	Eight pills blister-packed on a card; 14 cards in each package	One card per day for 14 days	112	14
Santyl	Manufacturer's dose calculator should be used to verify the quantity to dispense	Dependent on size of wound(s)	Per-dose calculator	Varies according to wound(s) size and severity

Federal Regulatory Requirements For Applicable Programs

The following terms are applicable to services provided by pharmacies to Navitus Members who receive benefits. The terms are a summarized subset from Navitus' current standard addendums for Payor benefits. These terms supersede any conflicting language in Agreements that have not been updated to reflect the terminology listed below.

A. Medicare Retail Services (including mail order)

1. **Definitions**
2. **Reimbursement**
3. **Authority; Locations; Compliance with Law; Internal Monitoring; and Credentialing**
   Participating Pharmacy shall, in accordance with 42 CFR §423.505(i)(4)(iv) to comply with all applicable Law and CMS instructions. Participating Pharmacy also shall, in accordance with 42 CFR §423.153(c)(1), comply with the standards for pharmacy practice as established by Law for its Locations. Participating Pharmacy and its pharmacists shall be duly licensed to practice pharmacy in each State or jurisdiction where it provides pharmacy services to Medicare Members. Evidence of such licensure shall be provided to Navitus upon request. Participating Pharmacy shall, in accordance with 42 CFR §§423.136 and 423.505(b)(14): (a) to comply with all Laws regarding the confidentiality, privacy, security and disclosure of medical records or other health and enrollment information, including, but not limited to the HIPAA Rules; (b) with respect to a Medicare Member's information, maintain procedures that specify how and why information is used within the organization and to whom and for what purposes information is disclosed outside the organization; (c) to ensure that medical information is released in accordance with applicable Law, including but not limited to, court orders and subpoenas; (d) to maintain such records and information in an accurate and timely manner; and (e) to ensure timely access by Medicare Members to the records and information that pertain to them.
4. **Participating Pharmacy Qualifications**
   4.1 Business Integrity; Governmental Investigations and Debarment. Participating Pharmacy further agrees to (as defined in 42 CFR §423.100) where its pharmacies are located; and Participating Pharmacy agrees to notify Navitus promptly and in writing of all investigations conducted by any State board of pharmacy or other Federal or State Governmental Authority in connection with the practice of pharmacy and all pending and final disciplinary actions by any such board or authority against Participating Pharmacy or any of its pharmacists.
   4.2 *Disclosure of Price Differentials*
   4.3 *Offering Covered Part D Drugs at the Calculated Price*
   4.4 *Compliance and Fraud Program and Complaints*
   4.5 *Delegation of Duties*
   4.6 *Sub-Delegation of Duties.*

5. **Monitoring**
6. **Billing and Payment**
7. **Member Protections**
8. **Monitoring: Audit Maintenance of Records**
9. **Term and Termination**

The services identified in Sections B, C, and D, below, are subject to the terms listed in Section A, above, in addition to the terms set forth in the sections below, unless such terms EXPRESSLY conflict with the terms in Section A.

B. Home Infusion Therapy Pharmacy Medicare Services

C. Long-Term-Care Pharmacy Medicare Services

The terms below are offered by Navitus on behalf of its Payors as a standard contract to any willing pharmacy that desires to provide Covered Pharmacy Services to long-term-care (LTC) residents (as defined below) and accepts these terms.[74] Nothing in these terms is intended, or shall be construed, to require, direct or permit: (a) the assignment or referral of any minimum or maximum number of LTC residents to Participating Pharmacy; or (b) the furnishing by Participating Pharmacy of Covered Pharmacy Services to any individual who is not a LTC resident of a LTC Facility that is affiliated or under contract with Participating Pharmacy.

1. **Definitions.** "LTC resident" means a Member who receives medical, assisted living and related services from a LTC Facility. Participating Pharmacy shall provide Navitus with complete and concise records of each LTC facility serviced by Participating Pharmacy.
2. **Dispensing Activities.** Participating Pharmacy agrees[75] to ensure that possession of the appropriate Part D Drug is transferred to each LTC resident, to verify the individual's eligibility each time a prescription is filled, to check its computer for information transmitted by Navitus about the individual's coverage, to perform quality assurance activities in accordance with to measure or mix Part D Drugs consistent with the underlying prescription orders, to fill containers for Part D Drugs when appropriate, to physically provide completed prescriptions to LTC residents and to maintain the facility and equipment necessary to operate each pharmacy Location.[76] Participating Pharmacy further acknowledges and agrees that it will meet the requirements of the Patient Protection and Affordable Care Act (PPACA) and regulations related to the short cycle dispensing of certain prescription orders.[77] Participating Pharmacy further agrees not to dispense to any Medicare Member any drug, for which Participating Pharmacy has obtained pricing or discounts under Section 340B of the Public Health Services Act.[78] Participating Pharmacy shall dispense Part

[74] 42 CFR §423.505(b)(18)
[75] 42 CFR §423.100
[76] 42 CFR §423.153(c)(2),
[77] 42 CFR Section 423.154
[78] 42 USC §256b

D Covered Products in regards to quantity dispensed[79] to Medicare Members who reside in LTC facilities[80] Participating Pharmacy must dispense solid oral doses of brand name drugs to Medicare Members in such facilities in not greater than fourteen (14) day increments.[81] Participating pharmacies shall be permitted to use uniform dispensing techniques for Part D Covered Products to Medicare Members in LTC facilities and Participating Pharmacy must collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event[82], and on the nature and quantity of unused brand and Generic Drugs[83] dispensed by Participating Pharmacy to Medicare Members residing in a LTC facility. Reporting on unused drugs is waived for drugs dispensed by participating pharmacies that dispense both brand and Generic Drugs, in no greater than 7-day increments for those participating pharmacies that attest to Navitus in writing of such dispensing procedures.

3. **Transition Process.** Participating Pharmacy acknowledges that each Medicare Plan provides transitional coverage for non-Formulary Prescription Drugs in a temporary supply, which is not less than thirty-one (31) days for LTC residents. Nothing in these terms is intended, or shall be construed, to create a differential transition process within any such Medicare Plan for some or all the Medicare Members who receive Covered Pharmacy Services from Participating Pharmacy. Participating Pharmacy agrees to cooperate with any process established by Navitus or its Payors for providing a transition for LTC residents who are stabilized on Prescription Drugs that are not on the relevant Formulary.[84]

4. **Performance and Services Criteria.**

4.1 Inventory. Participating Pharmacy shall maintain a comprehensive inventory of Part D Drugs commonly used in long-term care settings. Participating Pharmacy shall maintain a secured area for physical storage of drugs, with necessary added security as required by Federal and State Law for controlled substances. This section is not to be interpreted to require any inventory or security measures outside of those currently being done and performed in Participating Pharmacy's normal business setting.

4.2 Pharmacy Operations and Prescription Orders. Participating Pharmacy shall retain the services of a dispensing pharmacist so as to meet the requirements of pharmacy practice for dispensing Prescription Drugs to LTC residents. Such pharmacist shall conduct drug utilization reviews to screen routinely for allergies and drug interactions, to identify potential adverse reactions, identify inappropriate drug usage in the LTC resident population and promote cost effective therapy in the long-term care setting. In addition, Participating Pharmacy shall maintain pharmacy software and systems sufficient to meet the needs of Prescription Drug ordering and

[79] 42 CFR §423.154
[80] 42 CFR §423.100
[81] 42 CFR §423.4
[82] paragraph (a)(1) of section §423.154
[83] §423.4
[84] Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.4

distribution to such LTC facility. Participating Pharmacy shall provide its procedures manual (in written and electronic form) to Navitus and sufficient written copies of such manual to each LTC facility for use at its nurses' unit. Participating Pharmacy also shall provide each LTC facility and its staff ongoing training to assure that the LTC facility staff is proficient in Participating Pharmacy's processes for ordering and receiving medications. Participating Pharmacy shall be responsible for return and/or disposal of unused medications following discontinuance, transfer, discharge or death as permitted by the State boards of pharmacy. Controlled substances and out-of-date substances shall be disposed of within State and Federal guidelines.

4.3 Special Packaging. Participating Pharmacy shall maintain capacity sufficient to provide specific Prescription Drugs in unit-of-use packaging, bingo cards, cassettes, unit dose or other special packaging commonly required by LTC facilities. Participating Pharmacy shall maintain access to, or arrangements with a vendor to furnish supplies and equipment, including, but not limited to labels, auxiliary labels, and packing machines for furnishing drugs in such special packaging as required in the LTC setting.

4.4 Intravenous Medications. Participating Pharmacy shall maintain capacity sufficient provide intravenous ("IV") medications to LTC residents as ordered by a qualified medical professional. Participating Pharmacy shall maintain specialized facilities (i.e., a clean room) for the preparation of IV medications. Participating Pharmacy further shall furnish special equipment and supplies and IV-trained pharmacists and technicians as required to provide IV medications safely.

4.5 Compounding/Alternative Forms of Drug Composition. Participating Pharmacy shall provide specialized drug delivery formulations as required for LTC residents. Participating Pharmacy acknowledges that LTC residents may be unable to swallow or ingest medications through normal routes and may require tablets split or crushed or provided in suspensions or gel forms, to facilitate effective drug delivery, and Participating Pharmacy shall provide such services.

4.6 Pharmacist On-Call Service. Participating shall provide on-call, 24 hours-a-day, 7 days-a-week service with a qualified pharmacist available for handling calls after hours. Participating Pharmacy shall provide medication dispensing available for emergencies, holidays and after hours of normal operations.

4.7 Delivery Service. Participating Pharmacy shall provide for delivery of Part D Drugs to the LTC facility up to seven days each week (up to three times per day) and in-between regularly scheduled visits. Participating Pharmacy shall provide emergency daily service 24 hours-a-day, 7 days per week. Specific delivery arrangements will be subject to Agreement by Participating Pharmacy and the LTC facility. Participating Pharmacy shall provide safe and secure exchange systems for delivery of Part D Drugs to the LTC facility. In addition, Participating Pharmacy shall

provide medication cassettes, or other standard delivery systems, which may be exchanged on a routine basis for automatic restocking. Participating Pharmacy also shall deliver Part D Drugs to each LTC facility's carts as a part of routine "dispensing."

4.8 Emergency Boxes. Participating Pharmacy's shall provide "emergency" supplies of medications as required by the LTC facility in compliance with State requirements. Whenever possible, such "emergency" supplies shall include commonly prescribed Part D Drugs in accordance with each Medicare Plan's Formulary.

4.9 Emergency Log Books. Participating Pharmacy shall maintain a system for logging and charging medication used from emergency/first dose stock. Participating Pharmacy further agrees to maintain for each LTC resident a comprehensive record of such resident's medication order and drug administration.

4.10 Miscellaneous Reports, Forms; and Prescription Ordering Supplies. Participating Pharmacy shall provide reports, forms and prescription ordering supplies necessary for the delivery of quality pharmacy care in the LTC setting. Such reports, forms and prescription ordering supplies include, but are not limited to, provider order forms and monthly management reports to assist the LTC facility in managing orders, medication administration records, treatment administration records, interim order forms for new prescription orders and boxes/folders for order storage and reconciliation in the facility. Participating Pharmacy also shall provide reports, forms and information required to Navitus to the extent such information assists in satisfying any reporting requirements under the Patient Protection and Affordable Care Act (PPACA).

4.11Additional Performance Standards and Criteria. Participating Pharmacy shall comply with all other performance standards or criteria for its operations or services as, (i) established by CMS from time-to-time, (ii) established under any Law, including requirements of applicable State boards of pharmacy, and (iii) mutually agreed upon by Participating Pharmacy and Navitus from time-to-time or as provided in these terms.

5. **Full-Benefit Dual Eligible Individuals; Reimbursement of Cost Sharing Amounts.** In the event a LTC resident is a "full-benefit dual eligible individual" who meets the definition of an "institutionalized individual"[85], and is incorrectly charged a Cost Sharing Amount under a MA-PD Plan or a PDP, Navitus on behalf of such Medicare Plan shall work with Participating Pharmacy to provide Participating Pharmacy with direct reimbursement for any Cost Sharing Amounts not collected from such LTC resident; provided that Participating Pharmacy has not collected or waived such Cost Sharing Amounts, and, in fact, is carrying a debt for the amounts incorrectly

[85] 42 CFR §423.772

charged to such institutionalized individual; and provided, further that, Participating Pharmacy certifies the foregoing.[86]

6. **Waiver or Reduction of Cost-Sharing Amounts.** Participating Pharmacy may, to the extent expressly permitted by Law, waive or reduce a LTC resident's Cost Sharing Amount only if done in an unadvertised, unsolicited non-routine manner after determining in good faith that the LTC resident is financially needy or after failure to collect such amount despite reasonable efforts.[87] In the case of such a waiver or reduction on behalf of a LTC resident who is a subsidy eligible individual[88] Participating Pharmacy may waive or reduce such LTC resident's Cost Sharing Amount without regard to the standards set forth in the preceding sentence; provided, Participating Pharmacy does not advertise to, or solicit, LTC residents that such waivers or reductions are available.

   During a period of Low-Income Subsidy (LIS) retroactivity, Participating Pharmacy may choose to not collect the Cost Sharing Amount from the Medicare Member and carry the debt on behalf of the Medicare Member for claims during the period of LIS retroactive coverage. Participating Pharmacy shall keep documentation as to whether Participating Pharmacy collected the Cost Sharing Amount from the LIS-eligible Medicare Member, or if another party paid the Cost Sharing Amount on behalf of the Medicare Member, or if the Participating Pharmacy carried the debt for the Medicare Member during the LIS retroactive coverage period.

   If Participating Pharmacy collected the Cost Sharing Amount from the LIS-eligible Medicare Member for a claim during the period of LIS retroactive coverage, then Participating Pharmacy must reimburse the Medicare Member for the Cost Sharing Amount within fourteen (14) days of receiving reimbursement from Navitus. As part of the documentation it maintains, Participating Pharmacy shall record and provide the amount and date of reimbursement and the corresponding prescription number. During the period of LIS retroactive coverage, if the Participating Pharmacy did not collect the Cost Sharing Amount from the LIS-eligible Medicare Member and if the Participating Pharmacy carried the debt on behalf of the Medicare Member, Participating Pharmacy may keep the reimbursement from Navitus. Similarly, if the Participating Pharmacy waived or reduced the Cost Sharing Amount consistent with the safe harbor for pharmacy waiver or reduction in Cost Sharing Amount, then Participating Pharmacy must remit the waived or reduced amount to Navitus within fourteen (14) days. In the event that the LIS status change and the current Medicare Part D enrollment are both retroactive, and Navitus and benefit sponsor shall have no obligation to reimburse the Participating Pharmacy.

[86] 42 CFR §423.800
[87] 42 USC §§1320a-7a(i)(6)(A) and 1320a-7b(3)(G),
[88] 1860D-14(a)(3) of the Social Security Act

7. **Cooperation; Additional Contract Terms.** Participating Pharmacy shall cooperate with Navitus to ensure access to Part D Drugs by LTC residents, provide data and information to CMS and otherwise to effectuate the purposes of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) and its implementing regulations as well as provisions of the Patient Protection and Affordable Care Act (PPACA) and its implementing regulations. These terms may be modified to include other terms and conditions as CMS or Navitus may find necessary and appropriate to implement[89], including but not limited to, the electronic prescription standards[90] as well as provisions in MMA and PPACA implementing regulations that may pertain to Covered Pharmacy Services and dispensing of prescription orders to LTC residents.

8. **Access to LTC Facilities.** These terms shall be reasonably construed to provide LTC residents convenient access to long-term care pharmacies consistent with written policy guidelines and other CMS instructions and otherwise to effectuate the purposes of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) and its implementing regulations.[91]

9. **Claims Submission.** Navitus shall pay each funded, undisputed clean claim submitted by Participating Pharmacy, which is eligible for payment, within thirty (30) days of receipt of funding. Participating Pharmacy shall have not less than thirty (30) days, nor more than ninety (90) days, to submit claims to Navitus for reimbursement of such eligible claim.

   In no event shall payment be required to be made hereunder by Navitus pursuant to a claim received more than ninety (90) days from the date services are rendered, unless Participating Pharmacy notifies Navitus in writing within such period that a claim for such services has been presented to another Payor for payment and the applicable Payor continues to fund Navitus for claims. The Plan Specification for LTC benefits shall allow up to thirty-one (31) days of medication as a one-month's supply except as otherwise pertaining to provisions of the Patient Protection and Affordable Care Act (PPACA) and regulations promulgated related to the short cycle dispensing of certain prescription orders[92] and the provisions below which address claims and reimbursement relevant to the short cycle dispensing provisions.

D. Indian Health Services Including Medicare Part D Services

These terms[93] are offered by Navitus to all Indian Health Service pharmacies and I/T/U pharmacies[94], and apply special terms and conditions for the administration of the Medicare

[89] 42 CFR Subparts D and K
[90] 42 CFR §§423.159 and 423.505(b)(6)
[91] 42 CFR §423.120(a)(5)
[92] 42 CFR Section 423.154
[93] 42 CFR §423.120(a)(6)
[94] 42 CFR §423.100

Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations[95]. These terms supersede all such other provisions with regard to I/T/U pharmacies as described below.

Definitions
FTCA means the Federal Tort Claims Act, codified at 28 U.S.C. §§2671-2680.
IHCIA means the Indian Health Care Improvement Act[96]
IHS Provider means a service unit or units, including hospitals, health centers and one or more pharmacies or dispensaries, operated by the Indian Health Service.
Indian has the meaning given to that term in Section 4 of the IHCIA, 25 USC §1603.
Indian Health Service or "**IHS**" means the agency of that name within the U.S. Department of Health and Human Services[97]
ISDEAA means the Indian Self Determination and Education Assistance Act[98]
Indian Tribe has the meaning given that term in Section 4 of the IHCIA, 25 USC §1603.
Provider in this section includes the Indian Health Service (IHS) and all pharmacies and dispensaries operated by the IHS, or an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries, and is identified by name in an Indian Health Addendum
Tribal Organization has the meaning given that term in Section 4 of the IHCIA, 25 USC §1603.
Urban Indian Organization has the meaning given that term in Section 4 of the IHCIA, 25 USC §1603.

1. **Applicable Pharmacies.** The participating pharmacies for purposes of these terms include: (a) IHS Providers located within the geographic area covered by the provider Agreement where Indian Health Service units operate more than one pharmacy or dispensary, all such pharmacies and dispensaries are covered by these terms. (b) An Indian Tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the IHS[99]; (c) A Tribal Organization authorized by one or more Indian Tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract

[95] 42 CFR Parts 403, 411, 417, 422 and 423
[96] 25 U.S.C. §1601 et seq
[97] Sec. 601 of the Indian Health Care Improvement Act ("IHCIA"), 25 USC §1661
[98] 25 USC § 450 et seq
[99] ISDEAA, 25 USC §450 et seq

or compact with the IHS issued[100]; and (d) An Urban Indian Organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the IHS issued.[101]

2. **Deductibles.** The cost of pharmaceuticals provided at a pharmacy or dispensary of Participating Pharmacy or paid for by the Participating Pharmacy through a referral to a retail pharmacy shall count toward the Deductible and the annual out-of-pocket threshold applicable to an IHS Medicare Member enrolled in a Part D plan.

3. **Persons Eligible for Services of Participating Pharmacy.** An IHS provider is limited to serving eligible IHS and HIS Medicare Members[102] pursuant to, who are also eligible for Medicare Part D services.[103] The IHS provider may provide services to non-IHS eligible persons only under certain circumstances[104] and in emergencies.[105] Persons eligible for services of provider who is an Indian Tribe or a Tribal Organization or a provider who is an Urban Indian Organization shall be governed by the following authorities:

   (1) Title XVIII, Part D of the Social Security Act and 42 CFR Part 423; (2) IHCIA sections 813, 25 USC §1680c; (3) 42 CFR Part 136; and (4) The terms of the contract, compact or grant issued to provider by the IHS for operation of a health program. No clause, term or condition shall be construed to change, reduce, expand, or alter the eligibility of persons for services of the provider under the Part D plan that is inconsistent with the authorities identified in this section.

4. **Applicability of other Federal Laws.** The following Federal Laws and regulations apply to Participating Pharmacy, include but are not limited to the following:

   (a) A Participating Pharmacy that is an IHS Provider:
   (1) The Anti-Deficiency Act, 31 U.S.C. § 1341;
   (2) The ISDEAA, 25 U.S.C §450 et seq;
   (3) The FTCA, 28 U.S.C §2671-2680;
   (4) The Federal Medical Care Recovery Act, 42 U.S.C. §§ 2651-2653;
   (5) The Federal Privacy Act of 1974 ("Privacy Act"), 5 U.S.C. § 552a, 45C.F.R. Part 5b;
   (6) Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2;

[100] ISDEAA, 25 USC §450 et seq
[101] Title V of the IHCIA
[102] 42 CFR Part 136 and Section 813(a) and (b) of the IHCIA, 25 USC §1680 (a) and (b)
[103] Title XVIII, Part D of the Social Security Act and 42 CFR 423
[104] Section 813(c),
[105] Section 813(d), of the IHCIA

(7) The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 CFR Parts 160 and 164, and the HIPAA Rules; and
(8) The IHCIA, 25 U.S.C §1601 et seq.

(b) A Participating Pharmacy that is an Indian Tribe or a Tribal Organization:
(1) The ISDEAA, 25 U.S.C §450 et seq;
(2) The IHCIA, 25 U.S.C §1601 et seq;
(3) The FTCA, 28 U.S.C §2671-2680;
(4) The Privacy Act, 5 USC §552a and regulations at 45 CFR Part 5b; and
(5) HIPAA and the HIPAA Rules and regulations at 45 CFR parts 160 and 164; and
(6) Sec. 206(e)(3) of the IHCIA, 25 USC § 1624e(e)(3), regarding recovery from tortfeasors.

(c) A Participating Pharmacy that is an Urban Indian Organization:
(1) The IHCIA, 25 U.S.C §1601 et seq;
(2) The Privacy Act, 5 USC §552a and regulations at 45 CFR Part 5b; and
(3) HIPAA and the HIPAA Rules and regulations at 45 CFR parts 160 and 164; and
(4) Sec. 206(e)(3) of the IHCIA, 25 USC §1621e(e)(3), regarding recovery from tortfeasors, as made applicable to urban Indian organizations by Sec. 206(i) of the IHCIA.

5. **Non-Taxable entity.** To the extent Participating Pharmacy is a non-taxable entity, Participating Pharmacy shall not be required by Navitus or a Part D Plan Sponsor to collect or remit any Federal, State, or local tax.

6. **Insurance and indemnification.** As an IHS provider, FTCA coverage obviates the requirement that IHS carry private malpractice insurance as the United States consents to be sued in place of Federal employees for any damages to property or for personal injury or death caused by the negligence or wrongful act or omission of Federal employees acting within the scope of their employment.[106] Nothing in these terms shall be interpreted to authorize or obligate any IHS employee to perform any act outside the scope of his/her employment. The IHS provider shall not be required to acquire insurance, provide indemnification or guarantee that any Part D plan will be held harmless from liability. A Participating Pharmacy that is an Indian Tribe or a Tribal Organization shall not be required to obtain or maintain professional liability insurance to the extent such Participating Pharmacy is covered by the FTCA[107,108]. To the extent Participating Pharmacy is an Urban Indian Organization is covered by the FTCA[109], Participating Pharmacy shall not be required to obtain or maintain professional liability insurance. Further,

[106] 28 U.S.C. §§2671-2680
[107] Federal Law (Pub. L. 101-512, Title III, §314 as amended by Pub. L. 103-138, Title III, §308, codified at 25 USC §450 F note
[108] 25 CFR Part 900, Subpart M
[109] Section 224(g)-(n) of the Public Health Service Act, as amended by the Federally Supported Health Centers Assistance Act, Pub. L. 104-73, (codified as 42 U.S.C. §233(g)-(n)), and regulations at 42 C.F.R. Part 6

nothing in these terms shall be interpreted to authorize or obligate Participating Pharmacy or any employee of Participating Pharmacy to operate outside of the scope of employment of such employee, and Participating Pharmacy shall not be required to indemnify any Part D Plan Sponsor.

7. **Licensure.** States may not regulate the activities of IHS-operated pharmacies nor require that the IHS pharmacists be licensed in the State where they are providing services, whether the IHS employee is working at an IHS-operated facility or has been assigned to a pharmacy or dispensary of a tribe, tribal organization, or urban Indian organization. During the term of the Part D Plan Sponsor's Agreement, IHS pharmacists shall hold State Licenses in accordance with applicable Federal Law, and that the IHS facilities where the pharmacies and dispensaries are located shall be accredited in accordance with Federal statutes and regulations. During the term of the Part D Plan Sponsor's Agreement, the parties shall use the IHS facility's Drug Enforcement Agency (DEA) number consistent with Federal Law. Federal Law[110] provides that a pharmacist employed directly by a Participating Pharmacy that is an Indian tribe or tribal organization is exempt from the licensing requirements of the State in which the tribal health program is located, provided the pharmacist is licensed in any State. Federal Law[111] further provides that a health program operated by an Indian Tribe or Tribal Organization shall be deemed to have met a requirement for a License under State or local Law if such program meets all the applicable standards for such licensure, regardless of whether the entity obtains a License or other documentation under such State or local Law. Federal Laws apply to these terms. This provision shall not be interpreted to alter the requirement that a pharmacy hold a License from the Drug Enforcement Agency.

   To the extent that any directly hired employee of an Urban Indian Organization is exempt from State regulation, such employee shall be deemed qualified to perform services under the Part D Plan Sponsor's Agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. Federal Law[112] provides that a health program operated by an Urban Indian Organization shall be deemed to have met a requirement for a License under State or local Law if such program meets all the applicable standards for such licensure, regardless of whether the entity obtains a License or other documentation under such State or local Law. This provision shall not be interpreted to alter the requirement that a pharmacy hold a License from the Drug Enforcement Agency.

8. **Participating Pharmacy Eligibility for Payments.** To the extent that Participating Pharmacy is exempt from State licensing requirements, Participating Pharmacy shall not be required to hold a State License to receive any payments under these terms.

[110] Sec. 221 of the IHCIA
[111] Sec. 408 of the IHCIA
[112] Sec. 408 of the IHCIA

9. **Dispute Resolution.** For IHS provider, in the event of any dispute arising under these terms, the parties shall agree to meet and confer in good faith to resolve any such disputes. The Laws of the United States shall apply to any problem or dispute hereunder that cannot be resolved by and between the parties in good faith. Notwithstanding any provision in these terms to the contrary, IHS shall not be required to submit any disputes between the parties to binding arbitration. For Tribal and Urban providers, in the event of any dispute arising under these terms, the parties shall meet and confer in good faith to resolve any such disputes. Any dispute hereunder that cannot be resolved by and between the parties in good faith shall be submitted to the dispute resolution procedure pursuant to these terms.

10. **Governing Law.** These terms shall be governed and construed in accordance with Federal Law of the United States. In the event of a conflict between these terms and Federal Law, Federal Law shall prevail. Nothing in these terms shall subject Participating Pharmacy to State Law to any greater extent than State Law is already applicable.

11. **Pharmacy/Dispensary Participation.** These terms apply to all pharmacies and dispensaries operated by Participating Pharmacy. A pharmacy is required to use a National Provider Identifier (NPI) number.

12. **Acquisition of Pharmaceuticals.** Nothing in these terms shall affect Participating Pharmacy's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act. Nor shall anything in these terms require Participating Pharmacy to acquire drugs from Navitus, Part D Plan Sponsor, or from any other source.

13. **Drug Utilization Review; Generic Equivalent Substitution.** Where Participating Pharmacy lacks the capacity to comply with information technology requirements for drug utilization review and/or generic equivalent substitution set forth in these terms, Participating Pharmacy and Navitus agree that Participating Pharmacy shall comply with Part D Plan Sponsor's drug utilization review and/or generic equivalent substitution policies and procedures through an alternative method. Nothing in the paragraph shall be interpreted as waiving the applicability of drug utilization review and/or generic equivalent substitution policies and procedures adopted by Part D Plan Sponsor[113] as approved by CMS, to covered Part D Drugs dispensed by Participating Pharmacy to Medicare Members of Part D plans. The notification of price differentials is waived for Participating Pharmacy.[114]

[113] 42 CFR §423.153(b) and (c)
[114] 42 CFR §423.132(c)(3)

14. **Claims.** Participating Pharmacy may submit claims to Navitus on behalf of each Part D plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Participating Pharmacy shall submit a confirmation paper claim.

15. **Payment Rate.** Claims from Participating Pharmacy shall be paid at rates that are reasonable and appropriate.

16. **Information, Outreach, and Enrollment Materials.** (a) All materials for information, outreach or enrollment prepared for any Medicare Plan shall be supplied by Navitus to Participating Pharmacy in paper and electronic format at no cost to the Participating Pharmacy. (b) All marketing or informational material listing a provider as a pharmacy must refer to the special eligibility requirements necessary for service to be provided, consistent with the eligibility requirements as described in this Indian health addendum in paragraphs 5(a) for IHS providers and 5(b) for Tribal and Urban providers.

17. **Hours of Service.** Participating Pharmacy shall establish the hours of service of the pharmacies or dispensaries of Participating Pharmacy. At the request of Navitus, Participating Pharmacy shall provide written notification of its hours of service.

18. **Endorsement.** An endorsement of a non-Federal entity, event, product, service, or enterprise may be neither stated nor implied by the IHS provider or IHS employees in their official capacities and titles. Such agency names and positions may not be used to suggest official endorsement or preferential treatment of any non-Federal entity under these terms.

19. **Sovereign Immunity.** Nothing in these terms shall constitute a waiver of Federal or Tribal sovereign immunity.

CMS Standardized Denial Notice. Because IHS enrollees' prescription drugs, when dispensed through I/T/U pharmacies, are filled, and dispensed at no cost to the enrollee regardless of whether the drug is rejected at POS by the Part D plan, I/T/U pharmacies are exempt from the requirement to distribute the pharmacy notice.

Note: This exemption applies only to I/T/U pharmacies that dispense prescriptions at no cost to the enrollee. Any network commercial pharmacy providing services to IHS-eligible Part D enrollees must distribute the notice in accordance with the requirements in this section.[115]

[115] https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf

State Regulatory Requirements

Many states require managed care providers to comply with certain statutes and regulations when providing Covered Pharmacy Services to Members. The following Regulatory Appendix, attached, includes various regulations, requirements, and Laws ("Requirements") that may apply to the arrangement between Navitus, its Participating Pharmacy and/or Payors and the provision of applicable Covered Pharmacy Services by Participating Pharmacy.

Providers are required to comply with all applicable requirements; the provider Agreement is modified as set forth in the applicable state-specific provision. In the event that there is a conflict between a provision in the manual and a provision in the Regulatory Appendix, the provision in the Regulatory Appendix shall control. The Regulatory Appendix can be amended to reflect changes to the applicable Law(s).

Please refer to a state's website for the rules and requirements that pertain to Fee-for-Service Medicaid.

Alabama

- AUDIT LAWS/REGULATIONS
  Code of Alabama | Article 8 - Pharmacy Audit Integrity Act | Casetext
- BOARD OF PHARMACY
  http://www.albop.com/
- PHARMACY LAWS/REGULATIONS
  http://www.albop.com/ *(Click on "Resources" on top of page, then click on "Statutes & Rules")*

Alaska

- AUDIT LAWS/REGULATIONS
  Alaska Statutes 2020 (akleg.gov)
- BOARD OF PHARMACY
  Board of Pharmacy (alaska.gov)
- PHARMACY LAWS/REGULATIONS
  Statutes & Regulations, Board of Pharmacy, Professional Licensing, Division of Corporations, Business and Professional Licensing (alaska.gov)

Arizona

- AUDIT LAWS/REGULATIONS
  View Document (azleg.gov)
- BOARD OF PHARMACY
  Arizona State Board of Pharmacy(az.gov)
- PHARMACY LAWS/REGULATIONS

Arizona State Board of Pharmacy (Hover over "Resources" and click on "Rules and Statutes"

Arkansas

- AUDIT LAWS/REGULATIONS
  Arkansas Pharmacy Audit Bill of Rights
- BOARD OF PHARMACY
- Arkansas State Board of Pharmacy
- PHARMACY LAWS/REGULATIONS
  Pharmacy Lawbook – Arkansas State Board of Pharmacy

California

- AUDIT LAWS/REGULATIONS
  Bill Text - SB-1195 Audits of pharmacy benefits. (ca.gov)
- BOARD OF PHARMACY
  California State Board of Pharmacy
- PHARMACY LAWS/REGULATIONS
  Laws and Regulations - California State Board of Pharmacy
- DHCS Medi-Cal Two Plan Contract
  Organization and administration of the plan (ca.gov)

DHCS CALIFORNIA IMMUNIZATION REGISTRY (CAIR)

Pharmacies are to comply with the requirements for Member-specific immunization information, which is periodically reported to an immunization registry established in the PBM's Service Area(s) as part of the Statewide Immunization Information System.

Reports shall be made following the Member's initial health assessment and all other health care visits that result in an immunization being provided. Reporting shall be in accordance with all applicable state and federal Laws.

EMERGENCY SUPPLY

Navitus will ensure its Members have access to prior authorization (PA) medications in the event of an emergency when the parties needed to review a PA (clinical pharmacist and/or the provider) are not available.

If the Practitioner already sent the PA form to Navitus:

A Navitus representative will contact the PA queue by phone or email to request an expedited review and will notify the pharmacy if approved.

If the Practitioner sent the PA form to Navitus, but the PA team is not available, a Navitus representative will locate the request and see if it meets criteria:

If it meets criteria, a one-time override will be entered according to the coverage level on the PA form and the Formulary.

- An email will be sent to the PA team communicating that a one-time override was entered, so documentation can be entered into the PA record prior to reviewing the request and sending the proper notifications.

If it does not meet criteria, the on-call clinical pharmacist will be contacted to review the PA criteria and the information submitted.

- If approved, a one-time override will be entered according to the approved tier on the PA form or Formulary.
- An email will be sent by the PA team communicating the outcome of the discussion/decision so documentation can be entered into the PA record prior to reviewing the request and sending the proper notifications.

If the submitted form does not meet criteria and a pharmacist is not available, Navitus will allow the pharmacy to dispense a 5-day supply at no cost to the Member if the dispensing pharmacy deems it appropriate. The dispensing pharmacist must consider that the request could be denied, and the medication discontinued.

- If the Practitioner has not submitted the PA form, the pharmacy can dispense a 5-day supply at no cost to the Member.

The dispensing pharmacist or the Practitioner must determine whether it is appropriate for the Member to begin the PA medication in the event the PA request is denied, and the Member would then need to discontinue use.

- If the dispensing pharmacist/Practitioner deems it appropriate, Navitus will enter an override to allow a max Days' Supply of '5' and waive the Member pay amount (there is no cost to the Member).

- Navitus will fax the California universal form with the applicable criteria Document to the Practitioner's office with the Member information.

The pharmacist should be aware that receiving an emergent PA supply is not a guarantee that the PA will be approved and before dispensing, consider the effects if the Member having would need to discontinue the medication, should the request be denied.

HEALTH CARE PROVIDER BILL OF RIGHTS

Pharmacists have certain rights as a provider under Section 1375.7 of the California Health and Safety Code, also known as the Health Care Providers' Bill of Rights. The Health Care Providers' Bill of Rights prohibits a contract between a health care service plan and a health care provider from including a term authorizing the plan to change a material term of the contract unless the parties have agreed to it, or it is required to comply with state or federal law or with accreditation requirements of a private sector accreditation organization. It also provides other notice requirements related to material changes to a contract and other information regarding providers' rights. To view the complete Health Care Providers' Bill of Rights, visit Section 1375.7 of the California Health and Safety Code at the website for California Legislative Information.

PHARMACIST'S RIGHT TO SUBMIT COMPLAINT

- A provider may report to the department's Office of Plan and Provider Relations, either through the toll-free line (877-525-1295) or email address (plans-providers@dmhc.ca.gov), in instances where the provider believes a plan is engaging in unfair payment patterns. This is subject to the Department of Managed Health Care (DHMC) under §1371.39 of the California Health & Safety Code.

COMMUNICATION OF LESS COSTLY ALTERNATIVES

- Pursuant to Section 1385.003 of the California Health and Safety Code, a health care service plan is prohibited from including in a contract with a pharmacy provider or its contracting agent, a provision that prohibits the provider from informing a patient of a less costly alternative to a prescribed medication.

Colorado

- AUDIT LAWS/REGULATIONS
- Pharmacy Benefit Manager And Insurer Requirements | Colorado General Assembly
- BOARD OF PHARMACY
  Pharmacy HOME | Division of Professions and Occupations (colorado.gov)
- PHARMACY LAWS/REGULATIONS
  State Board of Pharmacy: Laws and Rules | Division of Professions and Occupations

Connecticut

- AUDIT LAWS/REGULATIONS
  AN ACT CONCERNING PHARMACY AUDITS.
- BOARD OF PHARMACY
- The Commission of Pharmacy (ct.gov)
- PHARMACY LAWS/REGULATIONS
  Microsoft Word - Drug Laws 4-15-14 WEB (2) (ct.gov)

Delaware

- AUDIT LAWS/REGULATIONS
  Chapter - Delaware General Assembly
- BOARD OF PHARMACY
  Board of Pharmacy - Division of Professional Regulation - State of Delaware
- PHARMACY LAWS/REGULATIONS
  2500 Board of Pharmacy (delaware.gov)

Florida

- AUDIT LAWS/REGULATIONS
  Chapter 465 - 2011 Florida Statutes - The Florida Senate (flsenate.gov) *(Scroll to 465.188)*
- BOARD OF PHARMACY
  Florida Board of Pharmacy-(floridaspharmacy.gov)
- PHARMACY LAWS/REGULATIONS
  Florida Board of Pharmacy » Links and Resources- Information (floridaspharmacy.gov) Click on "Florida Statutes & Administrative Codes"

Georgia

- AUDIT LAWS/REGULATIONS
  C:\pdf\153810.wpd (ga.gov)
- BOARD OF PHARMACY
  Georgia Board of Pharmacy
- PHARMACY LAWS/REGULATIONS
  Laws, Policies & Rules | Georgia Board of Pharmacy

Hawaii

- AUDIT LAWS/REGULATIONS
  SB975 (hawaii.gov)
- BOARD OF PHARMACY
  Professional & Vocational Licensing Division | Board Of Pharmacy (hawaii.gov)
- PHARMACY LAWS/REGULATIONS
  Hawaii Revised Statutes Chapter 461-Pharmacy

Idaho

- AUDIT LAWS/REGULATIONS
  SENATE BILL NO.1336 (2018) - Pharmacy, benefit managers (idaho.gov)
- BOARD OF PHARMACY
  Welcome to State Board of Pharmacy (idaho.gov)
- PHARMACY LAWS/REGULATIONS
  Pharmacy Code & Administrative Rules | State Board of Pharmacy (idaho.gov)

Illinois

- AUDIT LAWS/REGULATIONS
  Illinois General Assembly - Full Text of HB5591 (ilga.gov)
- BOARD OF PHARMACY
  State of Illinois | Department of Financial & Professional Regulation (idfpr.com)
- PHARMACY LAWS/REGULATIONS
  State of Illinois (idfpr.com) Under "Laws and Rules"

Indiana

- AUDIT LAWS/REGULATIONS
  In accordance with 760 Ind. Admin. Code 5-3-3, an auditor conducting a claims audit must comply with all of the following:
  (1) The contract under which the audit is performed must provide a description of audit procedures that will be followed.
  (2) For an onsite audit conducted at a pharmacy's location, the auditor that conducts the audit must provide written notice to the pharmacy or pharmacist at least fourteen (14) calendar days before conducting the initial onsite audit for each audit cycle.
  (3) The auditor must not interfere with the delivery of pharmacist services to a patient, and must use every effort to minimize inconvenience and disruption to pharmacy operations during the audit. This subdivision does not prohibit audits during normal business hours of the pharmacy.
  (4) If the audit requires use of clinical or professional judgment, the audit must be conducted by or in consultation with an individual licensed as a pharmacist under IC 25-26.
  (5) The auditor must allow the use of written or otherwise transmitted hospital, physician, or other health practitioner records to validate a pharmacy record.
  (6) The auditor must perform the audit according to the same standards and parameters that the auditor uses to audit all other similarly situated pharmacies.
  (7) The period covered by the audit must not exceed twenty-four (24) months after the date on which a claim that is the subject of the audit was submitted to or adjudicated by the pharmacy benefit manager, unless a longer period is required under federal or state law. The pharmacy must be permitted to resubmit electronically any claims disputed by the audit. Audit procedures must provide for a period of at least thirty (30) calendar days during which the pharmacy may resubmit a disputed claim.
  (8) The auditor must not schedule an audit to begin during the first seven (7) calendar days of a month without the voluntary consent of the pharmacy. The consent may not be mandated by a contract or other means.
  (9) Payment to the auditor for conducting the audit must not be based on a percentage of the amount recovered as a result of the audit.
  (10) Within twenty-four (24) hours of receiving the notice of an audit, a pharmacy may reschedule the audit to a date not more than fourteen (14) calendar days after the date

proposed by the auditor. However, if the auditor is unable to reschedule within the fourteen (14) calendar day period, the auditor must select and reschedule the audit for a date after the fourteen (14) calendar day period.

(11) The auditor must allow a pharmacy or pharmacist to produce documentation to address a discrepancy found during the audit.

In accordance with IC 27-1-24.5-22(b)(5), claims auditing procedures:

(A) May not use extrapolation or any similar methodology;

(B) May not allow for recovery by a PBM of a submitted claim due to clerical or other error where the patient has received the drug for which the claim was submitted;

(C) Must allow for recovery by a contracted pharmacy for underpayments by the PBM; and

(D) May only allow for the PBM to recover overpayments on claims that are actually audited and discovered to include a recoverable error.

- BOARD OF PHARMACY
  PLA: Indiana Board of Pharmacy
- PHARMACY LAWS/REGULATIONS
  Indiana Pharmacy Laws and Regulations
- MAC PRICING
  IC 27-1-24.5-22

(A) In accordance with Indiana Code, MAC pricing will be updated at least every seven (7) calendar days. Before the prescription drug is placed or continued on a MAC list, a pharmacy benefit manager shall determination that a prescription drug: Is not obsolete;

(B) Is generally available for purchase by pharmacies in Indiana from a national or regional wholesaler licensed in Indiana; and

(C) Is not temporarily unavailable, listed on a drug shortage list, or unable to be lawfully substituted.

A PBM shall establish a process for contracted pharmacies, pharmacy services administrative organizations, and group purchasing organizations to appeal, investigate, and resolve disputes regarding MAC pricing, including the requirement that the appeal be investigated and resolved within thirty (30) calendar days after the appeal is received.

If the appeal is denied, the MAC appeal process requires that the PBM do the following:

(A) Provide the reason for the denial.

(B) Provide the appealing contracted pharmacy, pharmacy services administrative organization, or group purchasing organization with the national drug code number of the prescription drug that is available from a national or regional wholesaler operating in Indiana.

If the appeal is approved, the MAC appeal process requires that the PBM do the following:

(A) Change the MAC of the drug for the pharmacy that filed the appeal as of the initial date of service that the appealed drug was dispensed.

(B) Adjusted the MAC of the drug for the appealing pharmacy and for all other contracted pharmacies in the same network of the PBM that filled a prescription for patients covered under the same health plan beginning on the initial date of service the appealed drug was dispensed.

(C) Notify each pharmacy in the PBM's network that the MAC for the drug has been adjusted as a result of an approved appeal.

(D) Adjust the drug product reimbursement for contracted pharmacies that resubmit claims to reflect the adjusted MAC, if applicable.

(E) Allow the appealing pharmacy and all other contracted pharmacies in the network that filled the prescriptions for patients covered under the same health plan to reverse and resubmit claims and receive payment based on the adjusted MAC from the initial date of service the appealed drug was dispensed.

(F) Make retroactive price adjustments in the next payment cycle unless otherwise agreed to by the pharmacy.

Iowa

- AUDIT LAWS/REGULATIONS
  191.59.pdf (iowa.gov)
- BOARD OF PHARMACY
  Iowa Board of Pharmacy
- PHARMACY LAWS/REGULATIONS
  Rules/Laws | Iowa Board of Pharmacy

Kansas

- AUDIT LAWS/REGULATIONS
  Statute | Kansas State Legislature (kslegislature.org)
- BOARD OF PHARMACY
  Kansas Board of Pharmacy - Homepage (ks.gov)
- PHARMACY LAWS/REGULATIONS
  Kansas Board of Pharmacy - Statutes - Regs (ks.gov)

Kentucky

- AUDIT LAWS/REGULATIONS
  statute.aspx (ky.gov)
- BOARD OF PHARMACY
  Kentucky Board of Pharmacy

- PHARMACY LAWS/REGULATIONS
  Kentucky Board of Pharmacy

Louisiana

- AUDIT LAWS/REGULATIONS
  Louisiana Laws - Louisiana State Legislature
- BOARD OF PHARMACY
  Louisiana Board of Pharmacy | State of Louisiana (la.gov)
- PHARMACY LAWS/REGULATIONS
  Louisiana Board of Pharmacy | State of Louisiana (la.gov)

Maine

- AUDIT LAWS/REGULATIONS
  Title 24-A, §4317: Pharmacy providers (mainelegislature.org)
- BOARD OF PHARMACY
  Board of Pharmacy | Office of Professional and Occupational Regulation (maine.gov)
- PHARMACY LAWS/REGULATIONS
  Board of Pharmacy - Laws & Rules (maine.gov)

Maryland

- AUDIT LAWS/REGULATIONS
  Article - Insurance, Section 15-1629 (maryland.gov)
- BOARD OF PHARMACY
  Pages - Maryland Pharmacy Board
- PHARMACY LAWS/REGULATIONS
  Pages - laws-regulation-legislation-reports (maryland.gov)

Massachusetts

- AUDIT LAWS/REGULATIONS
  Session Law - Acts of 2014 Chapter 441 (malegislature.gov)
- BOARD OF PHARMACY
  Board of Registration in Pharmacy | Mass.gov
- PHARMACY LAWS/REGULATIONS
  Laws and regulations of the Board of Registration in Pharmacy | Mass.gov

Michigan

- AUDIT LAWS/REGULATIONS
  standards for pharmacy auditing practices; (mi.gov)
- BOARD OF PHARMACY
  LARA - Pharmacy (michigan.gov)
- PHARMACY LAWS/REGULATIONS

LARA - Laws/Regulations (michigan.gov)

Minnesota

- AUDIT LAWS/REGULATIONS
  SF 278 5th Engrossment - 91st Legislature (2019 - 2020) (mn.gov) *(Scroll to Sec 12 "Pharmacy Audits")*
  BOARD OF PHARMACY
  Minnesota Board of Pharmacy / Minnesota Board of Pharmacy (mn.gov)
- PHARMACY LAWS/REGULATIONS
  Laws Rules Guidelines / Minnesota Board of Pharmacy (mn.gov)

Cash Payment for Medications

Hennepin Health will inform pharmacies and providers of members' right to pay cash for medications under certain circumstances. The list below describes the circumstances under which this is allowed. It is the pharmacist's and prescriber's responsibilities to document the event, using the form required by the Department of Human Services (Advance Member Notice of Noncovered Prescription (DHS-3641) (PDF). Hennepin Health does not require pharmacies or providers to submit the DHS-3641 form, but the form must be kept on file and be made available to Hennepin Health or the Department of Human Services upon request.
A pharmacy may accept cash payment for a noncovered prescription drug if **all** the following apply:
• The member is not enrolled in the restricted member program
• The pharmacist has reviewed all available covered alternatives with the member
• The pharmacy obtains an Advance Member Notice of Noncovered Prescription (DHS-3641) (PDF)
• The prescription is not for a controlled substance (other than weight loss medications that are not part of the Hennepin Health benefit, such as phentermine)
• The prescription is not for gabapentin

A pharmacy may accept cash payment for a controlled substance or gabapentin only if the pharmacy has received an Advance Member Notice of Noncovered Prescription (DHS-3641) (PDF) signed by the prescriber and all criteria has been met for a member who is not enrolled in the restricted member program. Hennepin Health will not authorize a pharmacy to accept cash if the medication requires prior authorization or is subject to a quantity limit and the prescriber has not attempted to obtain the prior authorization or authorization to exceed the quantity limit. Hennepin Health will authorize cash payment if the pharmacy and member complete their sections of the DHS-3641 and the prescriber confirms the following:
• Covered alternatives are not viable options for the member
• The prescriber is aware he/she is seeking authorization for the pharmacy to charge the member for the medication

• The prescriber is aware of the last time the medication was filled for the member, if applicable
• The prescriber attests that allowing the member to purchase the medication is medically necessary

The prescriber must sign the DHS-3641, send the completed form to the pharmacy and retain a copy of the completed form in the member's medical record. The pharmacy must also retain a copy of the completed form as documentation of approval from Hennepin Health to accept cash payment on the date of service. The completed DHS-3641 is authorization from Hennepin Health to accept cash payment on the date of service; you do not need to submit a copy to Hennepin Health unless requested. The prescriber or pharmacy does not need to call Hennepin Health for additional authorization.

In situations where Hennepin Health or PBM staff have concerns about the practices of a provider or pharmacy, or when possible abuse of the health care system by a member is suspected, Hennepin Health may ask for copies of the (DHS-3641) form(s) from pharmacists or clinics to determine if the process to allow for cash payments is functioning appropriately.

Mississippi

AUDIT LAWS/REGULATIONS
PBM_Audit_Integrity.pdf (ms.gov)

- BOARD OF PHARMACY
  Welcome to the Mississippi Board of Pharmacy (ms.gov)
- PHARMACY LAWS/REGULATIONS
  Regulations (ms.gov)

Missouri

- AUDIT LAWS/REGULATIONS
  Missouri Revisor of Statutes - Revised Statutes of Missouri, RSMo Section 338.600
- BOARD OF PHARMACY
  Board of Pharmacy (mo.gov)
- PHARMACY LAWS/REGULATIONS
  Board of Pharmacy rules/statutes (mo.gov)

Montana

- AUDIT LAWS/REGULATIONS
  SB0235.pdf (mt.gov)
- BOARD OF PHARMACY
  Board of Pharmacy (mt.gov)
- PHARMACY LAWS/REGULATIONS
  Statute/Rule Information (mt.gov)

Nebraska

- BOARD OF PHARMACY
  Pharmacy Professions (ne.gov)
- PHARMACY LAWS/REGULATIONS
  Pharmacy.pdf (ne.gov)
- 340B PHARMACIES
- Neb. Rev. Stat. 44-4609
  (1) A pharmacy benefit manager that reimburses a 340B entity or a 340B contract pharmacy for a drug that is subject to an agreement under 42 U.S.C. 256b shall not reimburse the 340B entity or the 340B contract pharmacy for the pharmacy-dispensed drug at a rate lower than that paid for the same drug to similarly situated pharmacies that are not 340B entities or 340B contract pharmacies, and shall not assess any fee, chargeback, or other adjustment upon the 340B entity or 340B contract pharmacy on the basis that the 340B entity or 340B contract pharmacy participates in the program set forth in 42 U.S.C. 256b.
  (2) A pharmacy benefit manager shall not discriminate against a 340B entity or 340B contract pharmacy in a manner that prevents or interferes with a covered individual's choice to receive such drug from the corresponding 340B entity or 340B contract pharmacy.
- MAC PRICING
- Neb. Rev. Stat. 44-4608
  (1) With respect to each contract and contract renewal between a pharmacy benefit manager and a pharmacy, the pharmacy benefit manager shall:
    (a) Update any maximum allowable cost price list at least every seven business days, noting any price change from the previous list, and provide a means by which a network pharmacy may promptly review a current price in an electronic, print, or telephonic format within one business day of any such change at no cost to the pharmacy;
    (b) Maintain a procedure to eliminate a product from the maximum allowable cost price list in a timely manner to remain consistent with any change in the marketplace; and
    (c) Make the maximum allowable cost price list available to each contracted pharmacy in a format that is readily accessible and usable to the contracted pharmacy.
  (2) A pharmacy benefit manager shall not place a prescription drug on a maximum allowable cost price list unless the drug is available for purchase by pharmacies in this state from a national or regional drug wholesaler and is not obsolete.
  (3) Each contract between a pharmacy benefit manager and a pharmacy shall include a process to appeal, investigate, and resolve disputes regarding any maximum allowable cost price. The process shall include:
    (a) A fifteen-business-day limit on the right to appeal following submission of an initial claim by a pharmacy;
    (b) A requirement that any appeal be investigated and resolved within seven business days after the appeal is received by the pharmacy benefit manager; and

(c) A requirement that the pharmacy benefit manager provide a reason for any denial of an appeal and identify the national drug code for the drug that may be purchased by the pharmacy at a price at or below the price on the maximum allowable cost price list as determined by the pharmacy benefit manager.

(4) If an appeal is determined to be valid by the pharmacy benefit manager, the pharmacy benefit manager shall:

(a) Make an adjustment in the drug price no later than one day after the appeal is resolved; and

(b) Permit the appealing pharmacy to reverse and rebill the claim in question, using the date of the original claim.

- GAG CLAUSE PROHIBITION
  Neb. Rev. Stat. 44-4606

  (1) A participation contract between a pharmacy benefit manager and any pharmacist or pharmacy providing prescription drug coverage for a health benefit plan shall not prohibit or restrict any pharmacy or pharmacist from or penalize any pharmacy or pharmacist for disclosing to any covered person any health care information that the pharmacy or pharmacist deems appropriate regarding:

  (a) The nature of treatment, risks, or an alternative to such treatment;

  (b) The availability of an alternate therapy, consultation, or test;

  (c) The decision of a utilization reviewer or similar person to authorize or deny a service;

  (d) The process that is used to authorize or deny a health care service or benefit; or

  (e) Information on any financial incentive or structure used by the health carrier.

  (2) A pharmacy benefit manager shall not prohibit a pharmacy or pharmacist from discussing information regarding the total cost for a pharmacist service for a prescription drug or from selling a more affordable alternative to the covered person if a more affordable alternative is available.

  (3) A pharmacy benefit manager contract with a participating pharmacist or pharmacy shall not prohibit, restrict, or limit disclosure of information to the director, law enforcement, or a state or federal governmental official, provided that:

  (a) The recipient of the information represents that such recipient has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and

  (b) Prior to disclosure of information designated as confidential, the pharmacist or pharmacy:

  (i) Marks as confidential any document in which the information appears; or

  (ii) Requests confidential treatment for any oral communication of the information.

  (4) A pharmacy benefit manager shall not terminate the contract with or penalize a pharmacist or pharmacy due to the pharmacist or pharmacy:

(a) Disclosing information about a pharmacy benefit manager practice, except information determined to be a trade secret, as determined by state law or the director; or

(b) Sharing any portion of the pharmacy benefit manager contract with the director pursuant to a complaint or a query regarding whether the contract is in compliance with the Pharmacy Benefit Manager Licensure and Regulation Act.

(5)

(a) A pharmacy benefit manager shall not require a covered person purchasing a covered prescription drug to pay an amount greater than the lesser of the covered person's cost-sharing amount under the terms of the health benefit plan or the amount the covered person would pay for the drug if the covered person were paying the cash price.

(b) Any amount paid by a covered person under subdivision (5)(a) of this section shall be attributable toward any deductible or, to the extent consistent with section 2707 of the federal Public Health Service Act, 42 U.S.C. 300gg-6, as such section existed on January 1, 2022, the annual out-of-pocket maximum under the covered person's health benefit plan.

- AUDIT LAWS/REGULATIONS

Neb. Rev. Stat. 44-4607

(1) Unless otherwise prohibited by federal law, an auditing entity conducting a pharmacy audit shall:

(a) Give any pharmacy notice fifteen business days prior to conducting an initial onsite audit;

(b) For any audit that involves clinical or professional judgment, conduct such audit by or in consultation with a pharmacist; and

(c) Audit each pharmacy under the same standards and parameters as other similarly situated pharmacies.

(2) Unless otherwise prohibited by federal law, for any pharmacy audit conducted by an auditing entity:

(a) The period covered by the audit shall not exceed twenty-four months from the date that the claim was submitted to the auditing entity, unless a longer period is required under state or federal law;

(b) If an auditing entity uses random sampling as a method for selecting a set of claims for examination, the sample size shall be appropriate for a statistically reliable sample;

(c) The auditing entity shall provide the pharmacy a masked list containing any prescription number or date range that the auditing entity is seeking to audit;

(d) No onsite audit shall take place during the first five business days of the month without the consent of the pharmacy;

(e) No auditor shall enter the area of any pharmacy where patient-specific information is available without being escorted by an employee of the pharmacy and, to the extent

possible, each auditor shall remain out of the sight and hearing range of any pharmacy customer;

(f) No recoupment shall be deducted from or applied against a future remittance until after the appeal process is complete and both parties receive the results of the final audit;

(g) No pharmacy benefit manager shall require information to be written on a prescription unless such information is required to be written on the prescription by state or federal law;

(h) Recoupment may be assessed for information not written on a prescription if:

(i)(A) Such information is required in the provider manual; or

(B) The information is required by the federal Food and Drug Administration or the drug manufacturer's product safety program; and

(ii) The information required under subdivision (i)(A) or (B) of this subdivision (h) is not readily available for the auditing entity at the time of the audit; and

(i) No auditing entity or agent shall receive payment based on a percentage of any recoupment.

(3) For recoupment under the Pharmacy Benefit Manager Licensure and Regulation Act, the auditing entity shall:

(a) Include consumer-oriented parameters based on manufacturer listings in the audit parameters;

(b) Consider the pharmacy's usual and customary price for a compounded medication as the reimbursable cost, unless the pricing method is outlined in the pharmacy provider contract;

(c) Base a finding of overpayment or underpayment on the actual overpayment or underpayment and not a projection that relies on the number of patients served who have a similar diagnosis, the number of similar orders, or the number of refills for similar drugs;

(d) Not use extrapolation to calculate the recoupment or penalties unless required by state or federal law;

(e) Not include a dispensing fee in the calculation of an overpayment, unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the pharmacy, or the identified overpayment is solely based on an extra dispensing fee;

(f) Not consider as fraud any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record. Such error may be subject to recoupment;

(g) Not assess any recoupment in the case of an error that has no actual financial harm to the covered person or health benefit plan. An error that is the result of the pharmacy failing to comply with a formal corrective action plan may be subject to recoupment; and

(h) Not allow interest to accrue during the audit period for either party, beginning with the notice of the audit and ending with the final audit report.

(4)(a) To validate a pharmacy record and the delivery of a pharmacy service, the pharmacy may use an authentic and verifiable statement or record, including a medication administration record of a nursing home, assisted-living facility, hospital, physician, or other authorized practitioner or an additional audit documentation parameter located in the provider manual.

(b) Any legal prescription that meets the requirements in this section may be used to validate a claim in connection with a prescription, refill, or change in a prescription, including a medication administration record, fax, e-prescription, or documented telephone call from the prescriber to the prescriber's agent.

(5) The auditing entity conducting the audit shall establish a written appeal process which shall include procedures for appealing both a preliminary audit report and a final audit report.

(6)(a) A preliminary audit report shall be delivered to the pharmacy within one hundred twenty days after the conclusion of the audit.

(b) A pharmacy shall be allowed at least thirty days following receipt of a preliminary audit report to provide documentation to address any discrepancy found in the audit.

(c) A final audit report shall be delivered to the pharmacy within one hundred twenty days after receipt of the preliminary audit report or the appeal process has been exhausted, whichever is later.

(d) An auditing entity shall remit any money due to a pharmacy or pharmacist as the result of an underpayment of a claim within forty-five days after the appeal process has been exhausted and the final audit report has been issued.

(7) Where contractually required, an auditing entity shall provide a copy to the plan sponsor of any of the plan sponsor's claims that were included in the audit, and any recouped money shall be returned to the health benefit plan or plan sponsor.

(8) This section does not apply to any investigative audit that involves suspected fraud, willful misrepresentation, or abuse, or any audit completed by a state-funded health care program.

Nevada

- BOARD OF PHARMACY
  Board of Pharmacy Home (nv.gov)
- PHARMACY LAWS/REGULATIONS
  Nevada Statues & Regulations (nv.gov)

New Hampshire

- AUDIT LAWS/REGULATIONS
  SB 0038 (state.nh.us)
- BOARD OF PHARMACY
  Board of Pharmacy | NH Office of Professional Licensure and Certification

- PHARMACY LAWS/REGULATIONS
  Board of Pharmacy Laws and Rules | NH Office of Professional Licensure and Certification

New Jersey

- AUDIT LAWS/REGULATIONS
  S2880 (state.nj.us)
- BOARD OF PHARMACY
  Pages - Board of Pharmacy (njconsumeraffairs.gov)
- PHARMACY LAWS/REGULATIONS
  Pages - Statutes and Regulations (njconsumeraffairs.gov)

New Mexico

- AUDIT LAWS/REGULATIONS
  59A ARTICLE 61.pdf (nmpharmacy.org) *(Search 61-11-18.2)*
- BOARD OF PHARMACY
  Pharmacy | NM RLD
- PHARMACY LAWS/REGULATIONS
  Pharmacy Rules and Laws | NM RLD

New York

- AUDIT LAWS/REGULATIONS
  Legislation | NY State Senate (nysenate.gov)
- BOARD OF PHARMACY
  NYS Pharmacy (nysed.gov)
- PHARMACY LAWS/REGULATIONS
  NYS Pharmacy:Laws, Rules & Regulations (nysed.gov)

North Carolina

- AUDIT LAWS/REGULATIONS
  Article_4C.pdf (ncleg.net)
- BOARD OF PHARMACY
  North Carolina Board of Pharmacy : NCBOP Homepage
- PHARMACY LAWS/REGULATIONS
  North Carolina Board of Pharmacy : Pharmacy Law and Rules (ncbop.org)

The North Carolina Department of Health and Human Services (NCDHHS) administers the North Carolina Managed Medicaid and North Carolina Health Choice (NCHC) programs within the State of North Carolina for the benefit of North Carolina residents.

Navitus is the prescription benefit management company for Alliance Health and Vaya Health, administering the North Carolina Managed Medicaid and North Carolina Health Choice (NCHC) pharmacy benefit on behalf of the respective managed care organization. Below are unique policies and/or procedures applicable to the North Carolina Managed Medicaid and North Carolina Health Choice (NCHC) programs, effective April 1, 2023.

Alliance Health Pharmacy Service Line 24/7.....855-759-9300

Alliance Health Member and Recipient Service Line 800-510-9132

Alliance Health Prior Authorization 855-759-9300

Vaya Health Pharmacy Provider Service Line 24/7.....800-540-6083

Vaya Health Member and Recipient Service Line 800-962-9003

Vaya Health Prior Authorization 800-540-6083

For additional Customer Service numbers, please see Navitus contact information.

Clinical Criteria:

Navitus and its pharmacy providers must follow the existing NC Medicaid and NC Health Choice Fee-for-Service clinical coverage policies and prior authorization (PA) criteria as described in:

(1) Clinical Coverage Policies: Required Pharmacy Clinical Coverage Policies below.
   a. 9: Outpatient Pharmacy
   b. 9A: Over-the-Counter Products
   c. 9B: Hemophilia Specialty Pharmacy Program
   d. 9D: Off Label Antipsychotic Safety Monitoring in Beneficiaries Through Age 17
   e. 1B: Physician Drug Program

(2) Prior Authorization Criteria: Drugs and/or drug classes requiring prior approval are available at https://www.navitus.com

Preferred Drug List (PDL):

Navitus provides access to covered outpatient drugs and biological agents through the PDL developed by NCDHHS. NCDHHS maintains one PDL for both Medicaid and NCHC programs. Navitus administers the PDL in a way that allows Members to access to all non-preferred drugs that are on the PDL through a structured prior authorization process.

The drug formulary, at minimum, includes:

(1) All drugs included the North Carolina Medicaid and NC Health Choice PDL as posted on the NCDHHS website. Navitus refers to the Pharmacy Services page on the NCDHHS website at: https://medicaid.ncdhhs.gov/pharmacy-services-clinical-coverage-policies, for a current listing of covered drugs on the North Carolina Medicaid and NC Health Choice PDL.
(2) All other covered drugs (Medicaid rebate eligible) in drug classes not listed on the NCDHHS PDL except for outpatient drugs excluded by state or federal policy, as defined in 42 C.F.R. § 438.3(s)(1).

Navitus furnishes covered benefits in an amount, duration, and scope no less than the amount, duration, and scope for the same services furnished to Members under NC Medicaid Direct. This includes all covered outpatient drugs for which the manufacturer has a CMS rebate agreement and for which the Department/NCDHHS provides coverage.

Alliance Health's PDL can be found at: https://www.alliancehealthplan.org/tp

Vaya Health's PDL can be found at: https://www.vayahealth.com

Covered Over the Counter (OTC) Products:

Below is a list of OTC products that are covered by Navitus. Covered OTC medications are subject to the same restrictions and recommendations as any legend drug. Restrictions and recommendations such as prior authorization and quantity limits may apply.

- smoking deterrent agents (nicotine)
- proton pump inhibitors
- second generation antihistamines
- second generation antihistamine-decongestant combination products (quantity limits apply)
- insulins
- syringes
- test strips
- control solutions
- lancets
- lancing devices
- pen needles
- oral contraceptives (levonorgestrel)
- polyethylene glycol 3350

Non-Covered Medications:

As defined in Clinical Coverage Policy 9, Navitus does not cover the following drugs and/or services:

- OTCs (except insulin and selected OTC products per Clinical Coverage Policy 9A, Over-The-Counter Products at https://medicaid.ncdhhs.gov/
- medical devices and supplies (these are covered as durable medical equipment)
- diaphragms (covered as a family planning service)
- DESI drugs
- compound equivalent to OTC products or DESI drugs
- fertility medications
- medications for cosmetic purposes
- medications for non-FDA approved uses
- drugs from manufacturers who have not signed a Drug Rebate Agreement
- inpatient hospital prescriptions
- drugs administered in the prescriber's office (These should be submitted by the prescriber using
- HCPCS codes on a medical claim)
- durable medical equipment
- prescriptions dispensed by providers who are not enrolled with Medicaid or NCHC
- IV fluids (dextrose 500 ml or greater) and irrigation fluids used in an inpatient facility (These should be billed by the facility as ancillary services)
- erectile dysfunction drugs
- weight loss and weight gain drugs
- drug samples
- drugs obtained from any patient assistance program
- drugs used for the symptomatic relief of cough and colds that contain expectorants or cough
- suppressants
- legend vitamins and mineral products with the exception of calcitriol(Vitamin D) when used for pre-dialysis, dialysis, or hypoparathyroidism treatment, prenatal vitamins, and fluoride.

Prior Authorizations (PA):

Prior authorization requires a Practitioner to receive pre-approval for coverage of select drugs under the terms of the Payor's pharmacy benefit plan. The purpose of Navitus' PA program is to:

- increase appropriate utilization of certain drugs
- promote the use of clinical guidelines
- actively manage the risk of using drugs with serious side effects
- positively influence the process of managing drug costs

Navitus utilizes the common PA request form(s), developed by NCDHHS and accepts PA requests via electronic submission, phone, fax, or U.S. mail.

Navitus has a web-based PA process, which provides an electronic review system accessible to providers. This is located at: https://providers.vayahealth.com/ or https://www.alliancehealthplan.org/tp/prescribers

Navitus will render a decision within 24 hours of receipt on all complete prior authorization requests. Preferred drugs will adjudicate as payable without prior authorization unless they are subject to clinical or administrative edits.

Prior Authorization forms for Alliance Health are located at: https://www.alliancehealthplan.org
Prior Authorization forms for Vaya Health are located at: https://www.vayahealth.com

Please see the Prior Authorization Section of this manual for additional information.

Early and Periodic Screening, Diagnosis and Treatment (EPSDT):

The EPSDT benefit entitles Medicaid beneficiaries under the age of 21 to medically necessary screening, diagnostic and treatment services within the scope of Social Security Act that are needed to "correct or ameliorate defects and physical and mental illnesses and conditions," regardless of whether the requested service is covered in the NC State Plan for Medical Assistance. This means that children under 21 years of age can receive services in excess of benefit limits or even if the service is no longer covered under the State Plan.

According to CMS, "ameliorate" means to improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Basic EPSDT criteria are that the service must be covered under 1905(a) of the Social Security Act, and that it must be safe, effective, generally recognized as an accepted method of medical practice or treatment, and cannot be experimental or investigational (which means that most clinical trials cannot be covered).

Requests for services for Medicaid-eligible children under the age of 21 will be reviewed using EPSDT criteria.

72-Hour Emergency Supply Available for Pharmacy Prior Authorization Drugs:

The 72-hour emergency supply should be dispensed any time the prior authorization process would result in inappropriate care for the Member's medical condition, member harm, or if a PA for a

formulary medication cannot be expeditiously resolved. If the prescribing provider cannot be reached or is unable to request a PA, the pharmacy should submit an emergency 72-hour prescription claim.

If the prior authorization request is not approved and an emergency supply is indicated, the system will bypass the prior authorization requirement. A "3" in the Level of Service field (418-DI) should be used to indicate that the transaction is an emergency fill.

There is no dispensing fee paid for an emergency fill. Copayments apply to all 72-hour emergency fills and only the drug cost will be reimbursed by Navitus to the pharmacy. The pharmacy is not limited in the number of times the emergency supply can be used for a Member pursuant to a valid prescription.

Appeals of Decisions to Deny Services:

Alliance

Appeals of decisions for Alliance Health Members should be submitted to Alliance Health. For more information, visit https://www.alliancehealthplan.org/members/information/rights/appeal/.

Vaya Health

Medicaid beneficiaries have a constitutional right to due process. Due process means you are entitled to a written notice and an opportunity to be heard by an impartial decisionmaker. Our Medicaid appeals system is based on this fundamental right to due process. A Medicaid appeal means "a request for review of an adverse benefit determination." Medicaid Members have the right to appeal Navitus' decisions to deny a Medicaid service because Medicaid is an entitlement program. Specifically, Medicaid Member have the right to appeal whenever they do not agree with an "Adverse Benefit Determination" made by Navitus regarding a request for services. An "appeal" is the request for review of an Adverse Benefit Determination.

An Adverse Benefit Determination as defined in federal law, means any of the following:

- The denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity,
- Appropriateness, setting, or effectiveness of a covered benefit
- The reduction, suspension or termination of a previously authorized service
- The denial, in whole or in part, of payment for a service
- The failure to provide services in a timely manner
- The failure of Navitus to act within the timeframes provided in 42 CFR 438.408(b)(1) and (2) regarding the standard resolution of grievances and appeals. Grievances are not appealable outside of the health plan.

If Navitus denies the request for service authorization or other Adverse Benefit Determination, the prescriber and Member will receive a letter by mail within fourteen (14) calendar days of the request for service for a request. The letter will provide a detail explanation for the denial decision and how to request an Appeal from Navitus if they disagree with the decision. If the Member or the Member's Representative requests an appeal by the deadline stated in the letter, the services may be able to continue through the end of the original authorization. The Notice of Adverse Benefit Determination sent to the Member or Member's Representative will explain how this "Continuation of Benefits" may be able to occur.

The Member or Member's Representative will receive a Notice of Adverse Benefit Determination and an appeal form. Prescribers will receive a copy of the Notice of Adverse Benefit Determination but will not receive the appeal form. Prescribers should understand the Medicaid Member due process and appeal rights so they can assist Members with filing an appeal, with the Member's written consent. Prescribers should never pressure or force a Member to file an appeal against the Member's wishes.

The first step when Navitus denies a request for Medicaid services is to ask for an appeal. The request for an Appeal must be filed with Navitus or the Managed Care Organization (MCO), depending on delegated responsibilities, within sixty (60) calendar days of the mailing date on the notice of adverse determination. An appeal means that someone at Navitus or the MCO who was not involved in the Member's case will take a second look at our decision about the Member's Medicaid services.

If the appeal request does not include enough information for Navitus to process the request (for example, the name, Medicaid Identification (MID) number or other identifying information), Navitus or the MCO will return the request without offering appeal rights. Upon receipt of a valid request for an appeal, an acknowledgement of the appeal notice will be mailed to the Member or Member's Representative within one (1) business day of the receipt of the appeal request.

Upon receipt of a request for an appeal that is not valid, a notification of an invalid appeal will be mailed to the Member or Member's Representative. This notification explains the reason the request is not valid and is mailed within one (1) business day of the receipt of the request for a Reconsideration.

When a standard appeal is requested, Navitus or the MCO has thirty (30) calendar days to make a reconsideration decision and send you a written notice, called a Notice of Resolution. Navitus or the MCO can extend this time frame for up to fourteen (14) days upon (i) request by Member or Member's Representative or provider on the Member's behalf, or (ii) if additional information is needed, the delay in obtaining that information is outside of Navitus' control, and the extension is in the Member's best interest. Navitus or the MCO will notify the Member or Member's Representative in writing before the expiration of the designated timeframe

and this Notice of Extension explains the Member's right to file a grievance if they disagree with Navitus' decision to extend the review timeframe.

Navitus or the MCO must provide the Member or Member's Representative the opportunity, before and during the appeals process, to examine the Member's case file, including medical records, and any other documents and records considered during the appeals process. Navitus will also give the Member or Member's Representative a reasonable opportunity to present evidence and allegations of fact or law, including evidence that was not presented at the time of the original request. The opportunity by the Member or Member's Representative to review the case file and submit additional information is explained in the appeal instructions and information that are mailed to the Member or Member's representative.

The Prior Authorization Criteria for Medicaid services authorized by Navitus can be found at:

- Prior Authorization forms for Alliance Health are located at: https://www.alliancehealthplan.org
- Prior Authorization forms for Vaya Health are located at: https://www.vayahealth.com

Vaya Members may call Navitus at 1-800-540-6083 to request a written copy of these documents by mail.

Alliance Health Members may call Navitus at 855-759-9300 to request a written copy of these documents by mail.

Members or the Member's Representative must request an appeal and receive a decision before they can request a State Fair Hearing.

Navitus does not provide bonuses or incentives to employees based directly on Member utilization or for decisions regarding member utilization. All utilization management determinations are based only on clinical appropriateness of care and services and existence of coverage for Navitus Members. The laws governing Medicaid Member appeals of Medicaid managed care decisions can be found at 42 CFR Part 438 and Chapter 108D of the North Carolina General Statutes.

In addition, Navitus will not attempt to influence, limit or interfere with an individual's right to file or pursue a grievance or request an appeal.

State Fair Hearing:

The Member or the Member's Representative may ask for a State Fair Hearing (SFH) any time up to one hundred twenty (120) calendar days after they receive the Notice of Plan Appeal Resolution letter from Navitus or the MCO. The Member or Member's Representative may ask for a State Fair Hearing only after they complete the Navitus or MCO appeal process.

The Member or Member's Representative may request for a State Fair Hearing by filling out the State Fair Hearing form that is included with the appeal decision letter sent by Navitus or the MCO. A Member or Member's Representative may mail, fax or call to submit their request for a State Fair Hearing.

Mail Request for a State Fair Hearing to:
Office of Administrative Hearings
1711 New Hope Church Road
Raleigh, NC 27609

Telephone: 1- 984-236-1860
Fax: 1- 984-236-1871

Frequently Asked Appeal Questions:

Q: How much time does an individual/guardian have to ask for an appeal?
A: The request for an appeal must be filed with Navitus or the MCO within sixty (60) calendar days of the mailing date on the notice of action sent by Navitus to the Member or the Member's Representative.

Q: How does a Member or Member's Representative ask for an appeal?
A: To request an appeal, complete the appeal form included with the Notice of Adverse Benefit Determination letter sent to the Member or Member's Representative and fax, email, mail the form to Navitus or the MCO at:

Alliance Health
Attention: Appeals Department
5200 W Paramount Pkwy, Ste 200
Morrisville, NC 27560
Telephone: 919-651-8641
Fax: 919-651-8682

Vaya Health
Navitus Health Solutions
Attention: Appeals/Grievance Coordinator
PO Box 999
Appleton, WI 54912-0999
Telephone: 800-962-9003

Fax: 1-855-673-6507

Q: Can the request be submitted over the phone?
A: Members or the Member's Representative may call Navitus or the MCO at 1-800-962-9003 if they want to make a request by phone, but they will still have to file a signed an appeal request within sixty (60) days after the mailing date of the notice of adverse benefit determination. If a Member or Member's Representative needs assistance with the form, they can contact Navitus at 1-800-962-9003 and someone will help him or her.

Q: Can a provider file the appeal?
A: A provider may help the Member or Member's Representative with completing the form and filing the appeal if the Member gives them written permission. There is a space on the form for the individual to identify someone who helped them with their appeal.

Q: What is the timeline for Navitus or the MCO to make a decision on the appeal request?
A: The appeal must be completed within thirty (30) calendar days after the request is filed. Navitus schedules a review with a clinical reviewer who has no prior involvement in the case. This person reviews the information used in making the decision, in addition to any new information that the Member or Member's Representative wishes to submit. New or additional information must be sent to Navitus within ten (10) calendar days of filing the appeal request form. Navitus mails a decision within thirty (30) calendar days.

Q: What if the Member needs the appeal to be processed faster?
A: A Member or Member's Representative may ask for an expedited appeal if waiting thirty days might seriously jeopardize the Member's life, health, or functional abilities. A provider or any other individual may also help ask for an expedited review if they have been authorized in writing to do so by the Member or Member's Representative. A written appeal request is not required for expedited appeal requested orally. If Navitus approves a request for an expedited appeal, Navitus will make reasonable efforts to provide oral and written notification of the determination within seventy-two (72) hours of the request.

Q: What if the request for expedited review is denied?
A: If Navitus denies a request for an expedited appeal, the Member will be called promptly informing them the expedited review was not approved, and Navitus will mail a notice within two (2) calendar days. The Member can contact Vaya Health at 1-800-962-9003 or Alliance Health at 800-510-9132 to file a grievance about the decision to deny expedited review. If the request for expedited review is denied, a decision on the appeal will be within the standard timeframe of thirty (30) calendar days. There is no need to resubmit appeal request.

Q: Will services be authorized during the appeal process?

A: If Navitus denies a Member's current Medicaid services before the authorization period ends, the Member may continue to receive services if they meet all of the following conditions:

- Appeal request is filed within ten (10) days of Navitus mailing the Notice of Adverse Benefit Determination
- The decision involves the denial of currently authorized services
- The services were ordered by an authorized provider
- The previous authorization period for the services has not expired
- The Member or Member's Representative requests that services continue

If all of these conditions are met, the Member will continue to be authorized for current services unless and until:

- The Member or Member's Representative withdraws the request for an appeal, or
- Ten days after we mail the appeal decision, unless the Member or Member's Guardian requests a State Fair Hearing within those ten (10) days, or
- The Member loses the State Fair Hearing, or
- The previous authorization period for the services expires or authorization service limits are met.
- For more details about continuation of benefits, see 42 C.F.R. § 438.420.

Q: What happens if the Member loses the appeal?
A: If the Member loses the appeal, Navitus is allowed to recover the cost of the Medicaid services received during the appeal process. We cannot recover these costs from individuals under eighteen (18), their parents or guardians, or providers.

Q: What if the Member or Member's Representative disagrees with the appeal decision?
A: If the Member or Member's Representative disagrees with the appeal decision, they may request a State Fair Hearing with the North Carolina Office of Administrative Hearings (OAH). Information explaining how to request a State Fair Hearing with OAH is enclosed with the appeal decision. The first step in a State Fair Hearing is the opportunity for mediation. Individuals and Providers can learn more about requesting a State Fair Hearing by visiting https://www.oah.nc.gov/hearings-division/medicaid-recipient-appeals.html or by calling 1-984-236-1850.

Credentialing requirements do not apply to pharmacies in the NC Medicaid network
Non-Discrimination Policy:

Navitus does not discriminate against any individual, provider, employee or other stakeholder due to race, age, religion/spiritual beliefs, sex, national origin, political affiliation, culture, and/or language, ability, handicap condition, sexual orientation,

socioeconomic status, or other personal beliefs. In addition, Navitus does not discriminate against pharmacies or providers that serve high-risk populations or specialize in conditions that require costly treatment.

Navitus does not permit contracted pharmacies (including staff, employees or independent contractors of such provider) to discriminate against any individual, provider, employee or other stakeholder due to race, age, religion/spiritual beliefs, sex, national origin, political affiliation, culture, and/or language, ability, handicap condition, sexual orientation, socioeconomic status, or other personal beliefs.

Grievance Process:

A grievance is an expression of dissatisfaction about any matter other than an adverse benefit determination. Grievances may include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the Pharmacies or Member's rights regardless of whether remedial action is requested.

A grievance may be submitted in the following ways:

Alliance Health
PHONE: Call Alliance Member and Recipient Services Monday through Saturday, 7 a.m. to 6 p.m at 800-510-9132. After these hours you may leave a message and we will contact you during the next business day.

MAIL: You can send a written complaint to
Alliance Health
Quality Management Department
Attn: Complaints and Grievances
5200 W. Paramount Parkway, Suite 200
Morrisville, NC 27560

EMAIL: Send an email to Complaints@AllianceHealthPlan.org

Vaya Health
PHONE: Call Vaya Member and Recipient Services Monday through Saturday, 7 a.m. to 6 p.m at 1-800-962-9003. After these hours you may leave a message and we will contact you during the next business day. You can also report concerns anonymously through Vaya's toll-free, 24/7 Compliance Hotline at 1-866-916-4255.

MAIL: You can send a written complaint to

Vaya Health
Grievance Resolution & Incidents Team
200 Ridgefield Court
Asheville, NC 28806

EMAIL: Send an email to ResolutionTeam@VayaHealth.com

ONLINE: Visit the Vaya EthicsPoint compliance portal at vayahealth.ethicspoint.com and you will be able to report anonymously.

Office of the Ombudsman:

Pharmacies may contact the NCDHHS Ombudsman Program for assistance with submitting a complaint about Navitus.

Pharmacies may call the NC Medicaid Ombudsman at 1- 877-201-3750. Pharmacies can also find more information about the NC Medicaid Ombudsman program and how to submit a complaint via: ncmedicaidombudsman.org

Cost Sharing:

- Medicaid is the payor of last resort. Pharmacies must bill all other third-party funds the Member has before submitting payment to Navitus. Examples of third-party funds include Medicare, private insurance, and Marketplace insurance.
- Pharmacies may not charge a Medicaid Member for services provided if Navitus denied authorization or reimbursement.
- Pharmacies may not require members to pay for any covered services other than the copayment amounts required under the State Plans.
- Consistent with 42 C.F.R. § 447.56, Medicaid cost sharing does not apply to a to the following Members: children under age twenty-one (21), pregnant women, individuals receiving hospice care, federally-recognized American Indians/Alaska Natives, BCCCP beneficiaries, foster children, disabled children under Family Opportunity Act, 1915(c) waiver beneficiaries, and an individual whose medical assistance for services furnished in an institution is reduced by amounts reflecting available income other than required for personal needs.
- The copay amount is returned in the pharmacy paid-claim response, Patient Pay Amount (Field 5Ø5-F5).
- Copayment Amounts:

Medicaid	
Prescription Type	Copay Amount
Generic and brand prescriptions (including OTC drugs)	$4/script

NC Health Choice beneficiaries with family incomes <159% FPL	
Prescription Type	Copay Amount
Generic and brand prescriptions	$3/script
Brand prescriptions when no generics available	$1/script
Brand prescriptions when generics available	$3/script
Over-the-counter medications	$1/script

NC Health Choice beneficiaries with family incomes <159% and <211% FPL	
Prescription Type	Copay Amount
Generic and brand prescriptions	$3/script
Brand prescriptions when no generics available	$1/script
Brand prescriptions when generics available	$10/script
Over-the-counter medications	$1/script

Additional reimbursement opportunities:

Additional Service Reimbursement		
Service Type	Reimbursement Amount	NCPDP Fields Required
*Mail Order Delivery	$1.50/Member/Pharmacy/Day	Level of Service (Field 418-DI) indicator equal to 06
Local Hand Delivery	$3/Member/Pharmacy/Day	Level of Service (Field 418-DI) indicator equal to 02
Immunization fee	Varies by vaccine type	
Long-Acting Injectable Antipsychotic Administration Fee	$17.36/administration	Level of Service (Field 418-DI) indicator equal to 05

*Retail pharmacies in the NC Medicaid network are not subject to limits on the volume of prescription orders mailed outside their local area.

North Dakota

- AUDIT LAWS/REGULATIONS
  ARTICLE 61-01 (nodakpharmacy.com) (page 194)
- BOARD OF PHARMACY
  North Dakota Board of Pharmacy (nodakpharmacy.com)
- PHARMACY LAWS/REGULATIONS
  North Dakota Board of Pharmacy (nodakpharmacy.com)

Ohio

- AUDIT LAWS/REGULATIONS
  Section 3901.811 - Ohio Revised Code | Ohio Laws
- BOARD OF PHARMACY
  State of Ohio Board of Pharmacy
- PHARMACY LAWS/REGULATIONS
  State of Ohio Board of Pharmacy

Oklahoma

- AUDIT LAWS/REGULATIONS
  Section 3901.811 - Ohio Revised Code | Ohio Laws
- BOARD OF PHARMACY
  Oklahoma State Board of Pharmacy - Home
- PHARMACY LAWS/REGULATIONS
  Oklahoma State Board of Pharmacy - Laws & Rules

Oregon

- AUDIT LAWS/REGULATIONS
  0570 (oregonlegislature.gov)
- BOARD OF PHARMACY
  Oregon Board of Pharmacy : Welcome Page : State of Oregon
- PHARMACY LAWS/REGULATIONS
  Oregon Board of Pharmacy : Laws & Rules : State of Oregon

Pennsylvania

- AUDIT LAWS/REGULATIONS
  2016 Act 169 - PA General Assembly (state.pa.us)
- BOARD OF PHARMACY
  Home (pa.gov)
- PHARMACY LAWS/REGULATIONS
  Board Laws and Regulations (pa.gov)

State Medicaid Contract
Participating Pharmacy shall comply with the terms of the contract between the Department of Human Services and the Payor ("State Medicaid Contract"), as applicable.

Data Submission
Participating Pharmacy shall cooperate with Payor to submit data for services within the timeframe and format required by the Department, no matter whether reimbursement for these services is made by Navitus either directly or indirectly through capitation. Penalties and sanctions will be imposed for failure to comply. The data is to be included in the utilization and encounter data provided to the Department in the format required.

Third Party Resource Identification
Participating Pharmacy will report all new third party resources to the Payor identified through the provision of medical services, which previously did not appear on the Department's recipient information files provided to the Payor.

Incentives
Any incentives provided by Participating Pharmacy must be limited to those permissible under the applicable Federal regulation.

Records
Participating Pharmacy must provide the Department with ready access to any and all documents and records of transactions pertaining to the provision of services to Medical Assistance consumers. Participating Pharmacy agrees to maintain books and records relating to the

HealthChoices Program services and expenditures, including reports to the Department and source information used in preparation of these reports. These records include but are not limited to financial statements, records relating to quality of care, medical records and prescription files.

Participating Pharmacy shall comply with all standards for practice and medical records keeping specified by the Commonwealth.

Participating Pharmacy, at its own expense, shall make all books, records, contracts, computers, or other electronic systems available for audit, review, evaluation or inspection by the Commonwealth, its designated representatives, CMS, the HHS Inspector General, the Comptroller General or their designees. Access must be granted either on-site, electronically or through the mail at the discretion of the reviewing entity. The right to audit exists for ten (10) years from the final date of the contract period; or from the date of completion of any audit, whichever is longer.

Audits

Participating Pharmacy must fully cooperate with any and all reviews and/or audits by state or federal agencies or their agents, such as the Independent Assessment Contractor, by assuring that appropriate employees and involved parties are available for interviews relating to reviews or audits. All records to be sent by mail shall be sent to the requesting entity in the form of accurate, legible paper copies, unless otherwise indicated, within fifteen (15) calendar days of such request and at no expense to the requesting entity. Such requests made by the Commonwealth shall not be unreasonable.

If the Commonwealth, CMS, or the HHS Inspector General or their designees determine that there is a reasonable possibility of fraud or similar risk, the Commonwealth, CMS, or the HHS Inspector General may inspect, evaluate, and audit Participating Pharmacy at any time.

Participating Pharmacy shall maintain books, records, documents and other evidence pertaining to all revenues, expenditures and other financial activity pursuant to this contract as well as to all required programmatic activity and data pursuant to this contract. Records other than medical records may be kept in an original paper state or preserved on micro media or electronic format. Medical records shall be maintained in a format acceptable by the Department. These books, records, documents and other evidence shall be available for review, audit or evaluation by authorized Commonwealth personnel or their representatives during the contract period and ten (10) years thereafter, except if an audit is in progress or audit findings are yet unresolved, in which case, records shall be kept until all tasks are completed.

Participating Pharmacy must retain the source records for its data reports for a minimum of ten (10) years and must have written policies and procedures for storing this information. Participating Pharmacy understands that payments for Medicaid services are made to Participating Pharmacy from federal and state funds. Additionally, Participating Pharmacy shall be held civilly and/or criminally liable to both the Payor, Navitus, and/or the Department, in the event of nonperformance, misrepresentation, fraud, or abuse.

False Claims and Statements

Participating Pharmacy is prohibited from submitting false claims and statements. Participating Pharmacy is subject to sanctions for the submission of false claims and statements.

Performance Review

Navitus shall monitor the Participating Pharmacy's performance on an on-going basis. Participating Pharmacy is subject to formal review according to a periodic schedule established by the Department, consistent with industry standards or State laws and regulations. If Navitus identifies deficiencies or areas needing improvement, Navitus and Payor may take corrective action.

Expensive Medical Conditions

Navitus cannot exclude or terminate Participating Pharmacy from participation in the Navitus' network due to the fact that the Participating Pharmacy has a practice that includes a substantial number of patients with expensive medical conditions.

Medically Necessary Care

"Medically Necessary" means a service, item, procedure, or level of care compensable under the Medical Assistance Program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Navitus may not exclude a Participating Pharmacy from Navitus' network because the Participating Pharmacy advocated on behalf of a Member for Medically Necessary and appropriate health care consistent with the degree of learning and skill ordinarily possessed by a reputable Health Care Provider practicing according to the applicable legal standard of care.

Participating Pharmacy is prohibited from denying services to a Member during the Pennsylvania Medical Assistance fee-for-service eligibility window prior to the effective date of enrollment with Payor.

Navitus cannot prohibit or restrict Participating Pharmacy from acting within the lawful scope of practice from discussing Medically Necessary care and advising or advocating appropriate medical care with or on behalf of a Member including; information regarding the nature of treatment options; risks of treatment; alternative treatments; or the availability of alternative therapies, consultation or tests that may be self-administered.

Navitus does not limit Participating Pharmacy from disclosure of medically necessary or appropriate health care information or alternate therapies to members, other health care professionals or the Department.

No Gag Clauses

Navitus cannot prohibit or restrict a Participating Pharmacy from acting within the lawful scope of practice from providing information the Member needs in order to decide among all relevant treatment options and the risks, benefits, and consequences of treatment or nontreatment.

Participating Pharmacy shall not limit its employee from the disclosure of information pertaining to the HealthChoices Program.

No Retaliation

Navitus cannot terminate a contract or employment with Participating Pharmacy for filing a grievance on a Member's behalf.

Moral or Religious Objections

This Agreement will not be construed as requiring Navitus to provide, reimburse for, or provide coverage of, a counseling or referral service if the Participating Pharmacy objects to the provision of such services on moral or religious grounds.

Participating Pharmacy must notify Navitus in in advance of Participating Pharmacy's conscience right, as applicable, and comply with the current Pennsylvania laws prohibiting discrimination on the basis of the refusal or willingness to provide health care services on moral or religious grounds as outlined in 40 P.S. §901.2121 and §991.2171; 43 P.S.§955.2 and 18 Pa. C.S. §3213(d).

Quality Management/Utilization Management

Participating Pharmacy will cooperate with Payors quality management/utilization management program standards as set forth in quality management and utilization management program requirements of the State Medicaid Agreement.

Insolvency or Cessation of Operations
Participating Pharmacy will continue to provide benefits to Members in the event of Payor's insolvency or other cessation of operations, including Members in an inpatient setting through the period for which the Capitation has been paid if applicable.

Non-Exclusivity
This Agreement does not prohibit Participating Pharmacy from contracting with another Payor or prohibit or penalize Payor or Navitus for contracting with other Participating Pharmacies.

Revisions
Navitus must make all necessary revisions to this Agreement to be in compliance with the requirements set forth in the State Medicaid Contract. Revisions may be completed as this Agreement become due for renewal provided that the Agreement is amended within one (1) year of the effective date of this Agreement with the exception of the encounter data requirements which must be amended immediately, if necessary, to ensure that Participating Pharmacy is submitting encounter data within the time frames specified in the State Medicaid Contract.

Audit Protocol
Participating Pharmacy must comply with all Medicaid rules, regulations, and guidance including the requirement that Participating Pharmacy agree to the audit and inspection authority of the Pennsylvania Office of Attorney General Medicaid Fraud Control Section pursuant to 42 C.F.R. §438.230(3) for services provided pursuant to the State Medicaid Contract.

Pennsylvania has a Medical Assistance Provider Self Audit Protocol which allows providers to voluntarily disclose overpayments or improper payments of Medical Assistance funds. This includes, but is not limited to inclusion in the provider handbooks. The protocol is available on the Department's Web site at https://www.dhs.pa.gov under "About" and "Fraud and Abuse."

Participating Pharmacy shall take such actions as are necessary to permit Payor to comply with the Fraud, Waste and Abuse requirements listed in the State Medicaid Contract as well as federal regulations including but not limited to 42 C.F.R. §438.608.

Navitus may will require Participating Pharmacy to comply with Pennsylvania Medical Assistance regulations and any enforcement actions directly initiated by the Department under its regulations, including termination and restitution actions.

Navitus may suspend payment to Participating Pharmacy when the Department determines there is a credible allegation of fraud against that network provider, unless the Department determines there is good cause for not suspending such payments pending the investigation.

Participating Pharmacy must grant the Department, CMS, the Pennsylvania Office of Attorney General Medicaid Fraud Control Section, HHS OIG, the Comptroller General, or their designees access to audit, evaluate, and inspect books, records, etc., which pertain to the delivery of or payment for Medicaid services under this Agreement. Participating Pharmacy must make such books, records, premises, equipment, staff etc. all available for an audit at any time. Right to inspect extends for ten (10) years after termination of the Agreement, or conclusion of an audit, whichever is later.

Overpayments

Navitus or Payor may audit, review and investigate Participating Pharmacy through prepayment and retrospective payment reviews. Navitus may cost avoid or recover any overpayments directly from its Participating Pharmacy or audits, reviews or investigations conducted solely by the Navitus or through network provider self-audits. The Department has the right to audit, review and investigate Participating Pharmacy. Navitus may recoup overpayments resulting from audits, reviews or investigations conducted independently by the Department, from the Participating Pharmacy after Navitus receives notice of the final findings from the Department. The Department may require Navitus to withhold payment to a Participating Pharmacy or to initiate a pre-payment review as a result of law enforcement reviews and activities or the Department's audits, reviews or investigations as required in 42 C.F.R. §§438.608(a)(8) and 455.23.

Compliance with Laws

Pursuant to 62 P.S. §449, Participating Pharmacy shall not prohibit its employees from the disclosure of information to or communicating with a managed care organization or the Department of Human Services ("Department") pertaining regarding this Agreement.

Participating Pharmacy shall make reasonable accommodation for Members with disabilities, in accordance with the Americans with Disabilities Act, for all services and shall assure physical and communication barriers shall not inhibit Members with disabilities from obtaining such services (42 U.S.C. Section 12101 et seq).

Participating Pharmacy agrees to comply with all applicable Medicaid, federal and state laws and regulations, including sub-regulatory guidance.

Participating Pharmacy will comply with Titles VI and VII of the Civil Rights Act of 1964, 42 U.S.C. §§2000d et seq. and 2000e et seq.; Title IX of the Education Amendments of 1972, 20 U.S.C. §§1681 et seq.; Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. §§701 et seq.; the Age

Discrimination Act of 1975, 42 U.S.C. §§6101 et seq.; the Labor Anti-Injunction Act, 42 P.S. §§206a206r; the Pennsylvania Labor Relations Act, 43 P.S. §§211.1-211.13; Section 1557 of the Patient Protection and Affordable Care Act (ACA), [42 C.F.R. 438.3(f)(1); 42 C.F.R. 438.100(d)]; the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Health Information Technology for Economic and Clinical Health c (HITECH) Act; the HIPAA Privacy Rule and the HIPAA Security Rule, 45 C.F.R.. Parts 160, 162, and 164 (HIPAA Regulations); the Pennsylvania Human Relations Act of 1955, 71 P.S. §§941 et seq.; Article XXI of the Insurance Company Law of 1921, as amended, 40 P.S. §§991.2102 et seq.; and Drug and Alcohol Use and Dependency Coverage Act 106 of 1989, 40 P.S. §§908-1 et seq.; Equal Employment Opportunity (EEO) provisions; Commonwealth's Contract Compliance Regulations that are set forth at 16 Pa. Code 49.101; all applicable laws, regulations, and policies of the Pennsylvania DOH and the PID; applicable Federal and State laws that pertain to Member rights and protections. Navitus may require Participating Pharmacy and its staff take those rights and protections into account when furnishing services to Members.

Department Oversight

Participating Pharmacy will make available to the Department upon request, data, clinical and other records and reports for review of quality of care, access and utilization issues including but not limited to activities related to External Quality Review, HEDIS®, Encounter Data validation, and other related activities.

Timeframe for Submission of Claims

Participating Pharmacy must submit claims to Navitus within one hundred eighty (180) days of the date of service.

Ownership Disclosures

Participating Pharmacy shall make full disclosure of ownership, management and control information as required by 42 CFR 455.100 through 455.106 to Navitus, within such time frames as necessary to allow Payor to comply with the disclosure obligations set forth in the State Medicaid Contract, including but not limited to, providing such information to Payor and/or Navitus within ten (10) business days after any change in ownership.

Rhode Island

- BOARD OF PHARMACY
  Pharmacy Licensing: Department of Health (ri.gov)
- PHARMACY LAWS/REGULATIONS
  webserver.rilin.state.ri.us/Statutes/TITLE5/5-19.1/INDEX.HTM

South Carolina

- AUDIT LAWS/REGULATIONS
  SC S0359 | 2019-2020
- BOARD OF PHARMACY
  SCLLR
- PHARMACY LAWS/REGULATIONS
  SCLLR Laws and Policies
- **Reimbursement Appeals**

  Pharmacies or pharmacists may request an external review of a denied internal appeal of provider reimbursements and appeals of recoupments arising out of audits conducted through its Pharmacy Benefits Manager (PBM). To be eligible for an External Review, pharmacies are required under South Carolina law to exhaust a PBM's internal appeal process prior to requesting an external review with the SCDOI. A pharmacy must then file the form, found within the link below, with the SCDOI within sixty (60) calendar days of the pharmacy's receipt of the PBM's final determination resolving the pharmacy's initial appeal or within thirty (30) calendar days of the pharmacy's receipt of the PBM's final audit report. Please utilize this link to access the form and for more information:
  https://www.doi.sc.gov/DocumentCenter/View/14693/Pharmacy-External-Review-Request-Form-53024-version

South Dakota

- AUDIT LAWS/REGULATIONS
  SDLRC - Codified Law 58-29F (sdlegislature.gov)
- BOARD OF PHARMACY
  South Dakota Board of Pharmacy - SD Dept. of Health
- PHARMACY LAWS/REGULATIONS
  SDLRC - Codified Law 36-11 (sdlegislature.gov)

Tennessee

- AUDIT LAWS/REGULATIONS
  Tennessee Code | Part 31 - Pharmacy Benefits Managers | Casetext
- BOARD OF PHARMACY
  Pharmacy (tn.gov)
- PHARMACY LAWS/REGULATIONS
  1140 - Board of Pharmacy (tnsosfiles.com)
- INITIAL APPEALS PROCESS (REIMBURSEMENT)
  0780-01-95
  The initial appeal process is available for all prescription drugs or devices in Tennessee for which a pharmacy alleges it did not receive its actual cost. Pharmacy must file an initial appeal

within seven business days of claim submission for reimbursement. Upon receipt of all required information, Navitus will review and make a final determination within seven business days. If Navitus fails to comply with applicable timing and notice requirements, initial appeal shall be resolved in favor of the pharmacy. If a pharmacy fails to comply with applicable timing requirements, Navitus may deny the initial appeal. Pharmacy is required to submit the name and contact information of the wholesaler or manufacturer from which the pharmacy purchased the drug or medical product or device.

Texas

The Texas Health and Human Services Commission (HHSC) administers the Texas Managed Care Medicaid program within the State of Texas for the benefit of Texas residents.

A number of health plans in the State of Texas chose Navitus as their prescription benefit management company to administer the Texas Managed Care Medicaid pharmacy benefit on behalf of the respective managed care organization. Below are unique policies and/or procedures applicable to the Texas Managed Care Medicaid program, effective March 1, 2012.

The CHIP reference in this manual also applies to CHIP perinate newborn Members, with noted exceptions.

Texas Provider Hotline 24/7.....877-908-6023 (toll-free)

Prior Authorization .....877-908-6023 (toll-free)

For additional Customer Service numbers, please see Navitus contact information.

Paper claims can be sent to:	Or faxed to:
Navitus Health Solutions Operations Division-Claims 1025 West Navitus Drive Appleton, WI 54913	855-668-8550

Network Acute Care Providers serving Medicaid Members must enter into and maintain a Medicaid provider agreement with HHSC or its agent to participate in the Medicaid Program, and must have a Texas Provider Identification Number (TPIN). All Network Providers, both CHIP and Medicaid, must have a National Provider Identifier (NPI) in accordance with the timelines established in 45 C.F.R. Part 162, Subpart D (for most Providers, the NPI must be in place by May 23, 2007.)

Network Provider understands and agrees that it may not interfere with or place any liens upon the state's right or the MCO's right, acting as the state's agent, to recovery from third party resources.

The Network Provider understands and agrees that HHSC is not liable or responsible for payment for Covered Services rendered pursuant to the Network Provider contract.
The Network Provider contracts must contain the MCO's process for terminating Provider contracts. For CHIP HMOs and managed care organizations participating in the CHIP Perinatal Program, the process must comply with the Texas Insurance Code and TDI regulations.

The MCO must follow the procedures outlined in applicable state and federal law regarding termination of a provider contract, including requirements of Insurance Code §843.306 and 28 Tex. Admin. Code § 11.901.

The Network Provider contracts must contain the MCO's process for terminating Provider contracts. For CHIP HMOs and managed care organizations participating in the CHIP Perinatal Program, the process must comply with the Texas Insurance Code and TDI regulations.

Network Provider may not offer or give anything of value to an officer or employee of HHSC or the State of Texas in violation of state law. A "thing of value" means any item of tangible or intangible property that has a monetary value of more than $50.00 and includes, but is not limited to, cash, food, lodging, entertainment, and charitable contributions. The term does not include contributions to public office holders or candidates for public office that are paid and reported in accordance with state and/or federal law. The MCO may terminate this Network Provider contract at any time for violation of this requirement.

72-Hour Override Emergency Prescription Supply

A 72-hour emergency supply of a prescribed drug must be provided when a medication is needed without delay and prior authorization (PA) is not available. This applies to all drugs requiring a prior authorization (PA), either because they are non-preferred drugs on the Preferred Drug List or because they are subject to clinical edits.
The 72-hour emergency supply should be dispensed any time a PA cannot be resolved within 24 hours for a medication on the Vendor Drug Program formulary that is appropriate for the member's medical condition. If the prescribing provider cannot be reached or is unable to request a PA, the pharmacy should submit an emergency 72-hour prescription.
A pharmacy can dispense a product that is packaged in a dosage form that is fixed and unbreakable, e.g., an albuterol inhaler, as a 72-hour emergency supply.

To be reimbursed for a 72-hour emergency prescription supply, participating pharmacies should submit the following information:

- "8" in Prior Authorization Type Code (Field 461-EU)
- "8Ø1" in Prior Authorization Number Submitted (Field 462-EV)

- "3" in Days' Supply (Field 4Ø5-D5, in the Claim segment of the billing transaction)
- The quantity submitted in Quantity Dispensed (Field 442-E7) should not exceed the quantity necessary for a three-day supply according to the directions for administration given by the prescriber. If the medication is a dosage form that prevents a three-day supply from being dispensed, e.g., an inhaler, it is still permissible to indicate that the emergency prescription is a three-day supply, and enter the full quantity dispensed.

- 72-hour Emergency Prescription Rejection Message
- The following message will be returned to pharmacies on all electronically submitted claims that the MCO rejects because the prior authorization criteria have not been met:
    - Prescriber should call 877-908-6023 or pharmacist should submit 72-hour Emergency Rx if prescriber not available.
    - Call 877-908-6023 for more information about the 72-hour emergency prescription supply policy.

Medication Synchronization

Medication Synchronization became effective September 1, 2018, for Texas Medicaid and applies to all Medicaid and CHIP managed care organizations (MCO). The MCO must establish a process by which the MCO, the member, the prescribing physician or health care provider, and a pharmacist may jointly approve a medication synchronization plan. A medication synchronization plan may be used only for prescribed drugs that treat chronic illnesses and comply with Texas Insurance Code Section 1369.453. Eligible drugs for medication synchronization must be covered by Medicaid or CHIP and in accordance with the VDP formulary and must meet all prior authorization criteria. Excluded drugs for medication synchronization are Schedule II controlled substances and Schedule III controlled substances containing hydrocodone.

Navitus' claim processing system has existing functionality to manage a member's medication synchronization plan via submission clarification codes (SCC). The usage of SCC by the pharmacist attests to the appropriate practices as specified by NCPDP standards and the medication synchronization plan. Additionally, the usage of SCC provides the pharmacy the ability to coordinate the member's prescription refills so the member can pick up prescriptions in accordance with the medication synchronization plan. Navitus' claim processing system has the functionality to allow for an applicable pro-rated cost share for CHIP members in accordance with the medication synchronization plan. Please note that per TAC §354.1867, dispensing fees will not be prorated.

Mailing/Delivering Prescriptions

- Per Texas HB 1763[116], a PBM may not as a condition of contract with a pharmacy prohibit a pharmacy from:

[116] 87(R) HB 1763

- Mailing or delivering a drug to a patient per patient's request, to the extent permitted by law; or
- Charging a shipping and handling fee for a mailed or delivered prescription as long as the pharmacist or pharmacy discloses to the patient before delivery:
  - The fee that will be charged; and
  - The fee will be reimbursable by the health plan or PBM

Member Communications

- The MCO is prohibited from imposing restrictions upon the Network Provider's free communication with a Member about the Member's medical conditions, treatment options, MCO referral policies, and other MCO policies, including financial incentives or arrangements and all managed care plans with whom the Network Provider contracts.

Pharmacy Directory

Pharmacies enrolled with Vendor Drug must update their information (i.e.: address, city, state, zip, phone, etc.) with the HHSC Administrative Services Contractor in a timely fashion or immediately upon request by the PBM. Navitus notifies pharmacies of issues/differences found and advises pharmacies to update their information with HHSC through the Provider Information Management System (PIMS) through My Account. Changes can take up to 30 business days to process.

Audit or Investigations [Network Provider] understands and agrees that the acceptance of funds under this contract acts as acceptance of the authority of the State Auditor's Office ("SAO"), or any successor agency, to conduct an investigation in connection with those funds. [Network Provider] further agrees to cooperate fully with the SAO or its successor in the conduct of the audit or investigation, including providing all records requested at no cost.

Cancellation of Product Orders

If a Network Provider offers delivery services for covered products, such as durable medical equipment (DME), home health supplies, or outpatient drugs or biological products, then the MCO's Provider Contract must require the Provider to reduce, cancel, or stop delivery at the Member's or the Member's authorized representative's written or oral request. The Provider must maintain records documenting the request.

For automated refill orders for covered products, the MCO's Provider Contract must require the Provider to confirm with the Member that a refill, or new prescription received directly from the physician, should be delivered. Further, the MCO must ensure that the Provider completes a drug regimen review on all prescriptions filled as a result of the auto-refill program in accordance with 22 Tex. Admin. Code § 291.34. The Member or Member's LAR must have the option to withdraw from an automated refill delivery program at any time.

Codes/Regulations

- Texas Administrative Code (state.tx.us)
- Texas Administrative Code RULE §353.4 (state.tx.us)
- Texas Administrative Code RULE §353.502 (state.tx.us)

The Network Provider understands and agrees that it is subject to all state and federal laws, rules, regulations waivers, policies and guidelines, and court-ordered consent decrees, settlement agreements, or other court orders that apply to the Network Provider Contract and the MCO's managed care contract with HHSC, the HMO Program, and all persons or entities receiving state and federal funds. The Network Provider understands and agrees that Att. B-1, §any violation by a provider of a state or federal law relating to the delivery of services pursuant to this Network Provider contract, or any violation of the MCO's contract with HHSC could result in liability for money damages, and/or civil or criminal penalties and sanctions under state and/or federal law.

The Network Provider understands and agrees that the following laws, rules, and regulations, and all subsequent amendments or modifications, apply to the Network Provider contract:
1. environmental protection laws:
a. Pro-Children Act of 1994 (20 U.S.C. §6081 et seq.) regarding the provision of a smoke-free workplace and promoting the non-use of all tobacco products;
b. National Environmental Policy Act of 1969 (42 U.S.C. §4321 et seq.) and Executive Order 11514 ("Protection and Enhancement of Environmental Quality") relating to the institution of environmental quality control measures;
c. Clean Air Act and Water Pollution Control Act regulations (Executive Order 11738, "Providing for Administration of the Clean Air Act and Federal Water Pollution Control Act with Respect to Federal Contracts, Grants, and Loans");
d. State Clean Air Implementation Plan (42 U.S.C. §740 et seq.) regarding conformity of federal actions to State Implementation Plans under §176(c) of the Clean Air Act; and
e. Safe Drinking Water Act of 1974 (21 U.S.C. §349; 42 U.S.C. §300f to 300j-9) relating to the protection of underground sources of drinking water;
2. state and federal anti-discrimination laws:
a. Title VI of the Civil Rights Act of 1964, (42 U.S.C. §2000d et seq.) and as applicable 45 C.F.R. Part 80 or 7 C.F.R. Part 15;
b. Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. §794); Americans with Disabilities Act of 1990 (42 U.S.C. §12101 et seq.); c. Age Discrimination Act of 1975 (42 U.S.C. §§6101-6107);
d. Title IX of the Education Amendments of 1972 (20 U.S.C. §§1681-1688);
e. Food Stamp Act of 1977 (7 U.S.C. §200 et seq.);
f. Executive Order 13279, and its implementing regulations at 45 C.F.R. Part 87 or 7 C.F.R. Part 16; and
g. the HHS agency's administrative rules, as set forth in the Texas Administrative Code, to the extent applicable to this Agreement.

3. The Immigration and Nationality Act (8 U.S.C. § 1101 et seq.) and all subsequent immigration laws and amendments;
4. the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law 104-191), and
5. the Health Information Technology for Economic and Clinical Health Act (HITECH Act) at 42 U.S.C. 17931 et.seq.

While performing the services described in the Network Provider contract, the Network Provider agrees to:
1. comply with applicable state laws, rules, and regulations and HHSC's requests regarding personal and professional conduct generally applicable to the service locations; and
2. otherwise conduct themselves in a businesslike and professional manner

Liability

In the event the MCO becomes insolvent or ceases operations, the Network Provider understands and agrees that its sole recourse against the MCO will be through the MCO's bankruptcy, conservatorship, or receivership estate.

The Network Provider understands and agrees that the MCO's Members may not be held liable for the MCO's debts in the event of the entity's insolvency." "The Network Provider understands and agrees that the Texas Health and Human Services Commission (HHSC) does not assume liability for the actions of, or judgments rendered against, the MCO, its employees, agents or subcontractors. Further, the Network Provider understands and agrees that there is no right of subrogation, contribution, or indemnification against HHSC for any duty owed to the Network Provider by the MCO or any judgment rendered against the MCO. HHSC's liability to the Network Provider, if any, will be governed by the Texas Tort Claims Act, as amended or modified (Tex. Civ. Pract. & Rem. Code §101.001 et seq.)

Network Provider shall maintain, during the term of the Network Provider contract, Professional Liability Insurance of $100,000 per occurrence and $300,000 in the aggregate, or the limits required by the hospital at which Network Provider has admitting privileges.
[NOTE: This provision will not apply if the Network Provider is a state or federal unit of government, or a municipality, that is required to comply with, and is subject to, the provisions of the Texas and/or Federal Tort Claims Act. This provision also will not apply to Nursing Facilities.]

Marketing

Network Provider agrees to comply with state and federal laws, rules, and regulations governing marketing. In addition, the Network Provider agrees to comply with HHSC's marketing policies and procedures, as set forth in HHSC's Uniform Managed Care Manual.

The Network Provider is prohibited from engaging in direct marketing to Members that is designed to increase enrollment in a particular health plan. The prohibition should not constrain Network Providers from engaging in permissible marketing activities consistent with broad outreach objectives and application assistance.

Community First Choice: Program Provider Responsibilities

- The CFC services must be delivered in accordance with the Member's service plan.
- The program provider must have current documentation which includes the Member's service plan, ID/RC (if applicable), staff training documentation, service delivery logs (documentation showing the delivery of the CFC services), medication administration record (if applicable), and nursing assessment (if applicable)
- The HCS or TxHmL program provider must ensure that the rights of the Members are protected (ex. e.g., privacy during visitation, to send and receive sealed and uncensored mail, to make and receive telephone calls, etc.).
- The program provider must ensure, through initial and periodic training, the continuous availability of qualified service providers who are trained on the current needs and characteristics of the Member being served.
    - This includes the delegation of nursing tasks, dietary needs, behavioral needs, mobility needs, allergies, and any other needs specific to the Member that are required to ensure the Member's health, safety, and welfare. The program provider must maintain documentation of this training in the Member's record.
- The program provider must ensure that the staff Members have been trained on recognizing and reporting acts or suspected acts of abuse, neglect, and exploitation. The program provider must also show documentation regarding required actions that must be taken when from the time they are notified that a DFPS investigation has begun through the completion of the investigation (ex. e.g., providing medical and psychological services as needed, restricting access by the alleged perpetrator, cooperating with the investigation, etc.). The program provider must also provide the Member/LAR with information on how to report acts or suspected acts of abuse, neglect, and exploitation and the DFPS hotline. (1-800-647-7418).
- The program provider must address any complaints received from a Member/LAR and have documentation showing the attempt(s) at resolution of the complaint. The program provider must provide the Member/LAR with the appropriate contact information for filing a complaint.
- The program provider must not retaliate against an employee, service provider, Member (or someone on behalf of a Member), or other person who files a complaint, presents a grievance, or otherwise provides good faith information related to the misuse of restraint, use of seclusion, or possible abuse, neglect, or exploitation.
- The program provider must ensure that the service providers meet all of the personnel requirements (age, high school diploma/GED OR competency exam and three references from non-relatives, current Texas driver's License and insurance if transporting, criminal history

check, employee misconduct registry check, nurse aide registry check, OIG checks). For CFC ERS, the program provider must ensure that the provider of ERS has the appropriate licensure.

- For CFC ERS, the program provider must have the appropriate licensure to deliver the service.
- For CFC, the program provider must ensure that any additional training requested by the Member/LAR of CFC PAS or habilitation (HAB) service providers is procured. [117]
- The use of seclusion is prohibited. Documentation regarding the appropriate use of restrictive intervention practices, including restraints must be maintained, including any necessary behavior support plans.
- The program provider must adhere to the MCO financial accountability standards.
- The program provider must prevent conflicts of interest between the program provider, a staff Member, or a service provider and a Member, such as the acceptance of payment for goods or services from which the program provider, staff Member, or service provider could financially benefit.
- The program provider must prevent financial impropriety toward a Member, including unauthorized disclosure of information related to a Member's finances and the purchase of goods with the Member's funds that a Member cannot use.

MCO Responsibilities

The MCO will initiate and maintain any action necessary to stop a Network Provider or employee, agent, assign, trustee, or successor-in-interest from maintaining an action against HHSC, an HHS Agency, or any Member to collect payment from HHSC, an HHS Agency, or any Member, excluding payment for non-covered services. This provision does not restrict a CHIP Network Provider from collecting allowable copayment and deductible amounts from CHIP Members. Additionally, this provision does not restrict a CHIP Dental Network Provider from collecting payment for services that exceed a CHIP Member's benefit cap.

Cost Sharing (CHIP ONLY)

- CHIP network pharmacies and out-of-network pharmacies may collect Copayments authorized in the CHIP State plan from CHIP Members. Copayments are the only amounts that Network Providers may collect from CHIP Members, except for costs associated with unauthorized non-emergency services provided to a Member by out-of-network providers for non-covered services. CHIP families that meet the enrollment period cost-share limit requirement must report it to the HHSC Administrative Service Contractor. The HHSC Administrative Service Contractor notifies the MCO that a family's cost-share limit has been reached.
- CHIP Cost-Sharing Schedule[118]

[117] CFR §441.565

[118] https://hhs.texas.gov/sites/default/files/documents/laws-regulations/handbooks/umcm/6-3.pdf

- The copay amount is returned in the pharmacy paid-claim response, Patient Pay Amount (Field 5Ø5-F5). No Copayments for MMC Members, CHIP perinate Members, CHIP perinate newborn Members, and CHIP Members who are Native Americans or Alaskan Natives. Additionally, for CHIP Members, there is no cost-sharing on benefits for well-baby and well-child services, preventive services, or pregnancy-related assistance.
- CHIP Member Prescriptions
  - CHIP Members are eligible to receive an unlimited number of prescriptions per month and may receive up to a 90-Day supply of a drug for certain maintenance medications.

Dispensing Limitations

Participating pharmacies must submit claims for reimbursement for the amount actually dispensed at the point of sale in the "Quantity Dispensed" field (442-E7). Participating pharmacies must dispense the quantity prescribed or ordered by the prescriber as allowed by State Law or benefit design limitation put forward by the managed care plan. Many National Drug Code (NDC) numbers are packaged in a size that is not a whole number. When entering a claim for a drug that is packaged in a metric decimal sized package (i.e., 1Ø.2; 2.5; 6.8; etc.), be sure to include the decimals on your claims and do not round up. For example, if you dispense one 1Ø.2 gm inhaler, you should be entering "1Ø.2" in the "Quantity Dispensed" field. The same goes for inhalers where the package quantity is 12.9 gm for 1 inhaler. When dispensing ophthalmic drops be sure to include the decimal quantity and do not round up.

Fraud, Waste and Abuse

The Network Provider understands and agrees to the following:
1. HHSC Office of Inspector General ("OIG") and/or the Texas Medicaid Fraud Control Unit must be allowed to conduct private interviews of Network Providers and their employees, agents, contractors, and patients;
2. requests for information from such entities must be complied with, in the form and language requested;
3. Network Providers and their employees, agents, and contractors must cooperate fully with such entities in making themselves available in person for interviews, consultation, grand jury proceedings, pre-trial conference, hearings, trials and in any other process, including investigations at the Network Provider's own expense; and
4. compliance with these requirements will be at the [Network Provider's] own expense.
The Network Provider understands and agrees to the following:
1. Network Providers are subject to all state and federal laws and regulations relating to fraud, abuse or waste in health care or dental care and the Medicaid and/or CHIP Programs, as applicable;
2. Network Providers must cooperate and assist HHSC and any state or federal agency that is charged with the duty of identifying, investigating, sanctioning or prosecuting suspected fraud, abuse or waste;
3. Network Providers must provide originals and/or copies of any and all information as requested by HHSC or the state or federal agency, allow access to premises, and provide records to the Office of Inspector General, HHSC, the Centers for Medicare and Medicaid Services (CMS), the U.S. Department of Health and Human Services,FBI, TDI, the Texas Attorney General's
Medicaid Fraud Control Unit or other unit of state or federal government, upon request, and free-of-charge;
4. If the Network Provider places required records in another legal entity's records, such as a hospital, the Network Provider is responsible for obtaining a copy of these records for use by the above-named entities or their representatives; and
5. Network Providers must report any suspected fraud or abuse including any suspected fraud and abuse committed by the MCO or a Member to the HHSC Office of Inspector General.
If the Network Provider receives annual Medicaid payments of at least $5 million (cumulative, from all sources), the Network Provider must:
1. Establish written policies for all employees, managers, officers, contractors, subcontractors, and agents of the Network Provider. The policies must provide detailed information about the False Claims Act, administrative remedies for false claims and statements, any state laws about civil or criminal penalties for false claims, and whistleblower protections under such laws, as described in Section 1902(a)(68)(A) of the Social Security Act.
2. Include as part of such written policies detailed provisions regarding the Network Provider's policies and procedures for detecting and preventing Fraud, Waste, and Abuse.

3. Include in any employee handbook a specific discussion of the laws described in Section 1902(a)(68)(A) of the Social Security Act, the rights of employees to be protected as whistleblowers, and the Provider's policies and procedures for detecting and preventing Fraud, Waste, and Abuse.

DME/Diabetic Supplies

Please consult the Texas Medicaid Provider Procedures Manual, Durable Medical Equipment (DME) and Comprehensive Care Program (CCP) sections, and Navitus Health Solution's Pharmacy Provider Manual page 135 for information regarding the scope of coverage durable medical equipment (DME) and other products commonly found in a pharmacy. For qualified children, this includes medically necessary over-the-counter drugs, diapers, disposable/expendable medical supplies, and some nutritional products. It also includes medically necessary nebulizers, ostomy supplies or bed pans, and other supplies and equipment for all qualified Members. Navitus Health Solutions encourages pharmacy participation in providing these items to Medicaid clients.

To be reimbursed for DME or other products normally found in a pharmacy, but not covered as a pharmacy benefit for children (birth through age 20), a pharmacy must:

- Enroll with the MCO to become a Medicaid-enrolled DME provider.

    - A limited set of basic home health supplies are available under the Vendor Drug Program (VDP) Formulary. Pharmacies will be reimbursed for filling prescriptions for supplies for clients in the Medicaid program. The list of supplies can be found on the Limited Home Health Supplies (LHHS) page on the VDP website at Vendor Drug Program (txvendordrug.com)
    - Pharmacies do not have to be enrolled as DME providers to submit claims for these supplies.

      Call Navitus at 877-908-6023 for information about DME and other Covered Products commonly found in a pharmacy for children (birth through age 20)

Health Resources and Services Administration 340B Discount Drug Program

The MCO must use a shared-savings approach for reimbursing Network Providers that participate in the federal Health Resources and Services Administration's (HRSA's) 340B discount drug program.

The MCO through its Provider Contract must require a 340B-covered entity seeking to use 340B stock to contract with the MCO as a 340B pharmacy and accept the payment terms of the MCO's shared-savings model. If the 340B covered entity does not accept the terms of the MCO's shared savings model for the reimbursement of 340B-purchased drugs, then the MCO may contract with the covered entity as a retail pharmacy. If the covered entity contracts with the MCO as a retail pharmacy, the MCO must prohibit the entity from using 340B-purchased drugs.

The MCO cannot require a Network Provider to submit its actual acquisition cost (AAC) on outpatient drugs and biological products purchased through the 340B program, consistent with UMCM Chapter 2. In addition, the MCO cannot impose PA requirements based on non-preferred status ("PDL PAs") for these drugs and products.

Payment Cycle

- Clean claims for outpatient pharmacy benefits must be adjudicated no later than: (1) 18 days after receipt if submitted electronically, or (2) 21 days after receipt if submitted non-electronically. Once a clean claim is received for a pharmacy claim, the MCOs are required, within the periods described above, to: (1) pay the total amount of the claim, or part of the claim, in accordance with the contract, (2) deny the entire claim, or part of the claim, and notify the provider why the claim will not be paid.
- Payment is considered to have been paid on the date of: (1) the date of issue of a check for payment and its corresponding EOB to the provider by the MCO, or (2) electronic transmission, if payment is made electronically.
- The MCO must notify Network Providers in writing of any changes in the list of claims processing or adjudication entities at least 90 Days prior to the effect date of change.
- The MCO's provider agreement must specify that program violations by the Health and Human Services Commission Office of Inspector General (OIG) as specified in 1 Tex. Admin. Code, Chapter 371, Sub chapter G.

Pharmacy Claims Manual: Pharmacy Claims Manual (texas.gov)

Family Planning

- If a member requests contraceptive services or family planning services, the Network Providers must also provide the Member counseling and education about family planning and available family planning services. Network Providers cannot require prenatal consent for Members who are minors to receive family planning services. Network Providers must comply with the State and Federal laws and regulations governing Member confidentiality (including minors) when providing information on family planning services to Members.

Preferred Drug List (PDL)/Formulary

- Navitus adheres to the HHSC Formulary and PDL for Managed Medicaid
- Texas Medicaid maintains a Preferred Drug List (PDL) comprised of various therapeutic classes. Prescriptions written for preferred drugs will be available without prior authorization, unless they are subject to clinical or administrative edits, while non-preferred drugs will require prior authorization.
  - Texas Medicaid STAR/CHIP/STAR Kids Formulary - TX STAR CHIP - Formulary (navitus.com)
  - Texas HHSC Vendor Drug Preferred Drug List (PDL) - Preferred Drugs | Vendor Drug Program (txvendordrug.com)
  - Texas HHSC Vendor Drug Formulary - Formulary | Vendor Drug Program (txvendordrug.com)

Prior Authorization

- TX STAR CHIP - Prior Authorization Forms (navitus.com)
- Payors must adhere to the formulary and PDL for Medicaid. Preferred drugs must adjudicate as payable without prior authorization unless they are subject to clinical or administrative edits.
- Navitus may require that the prescriber's office request prior authorization as a condition of coverage or payment for a Prescription Drug provided that: 1) A decision to approve or deny the prescription is made within 24 hours of the prior authorization request, and 2) If a Member's prescription for a medication is not filled with a prescription is presented to the pharmacist due to a prior authorization, the pharmacist must dispense a 72-hour emergency supply of the prescribed medication if the prescriber cannot be reached. The pharmacy may fill consecutive 72-hour supplies if the prescriber remains unavailable. Navitus will reimburse the pharmacy for dispensing the temporary supply of medication. The requirement that the Member be given at least a 72-hour supply for a new medication does not apply when the dispensing pharmacist determines that the taking the prescribed medication would jeopardize the health or safety of the Member. In such event, Payors will require that the Participating Pharmacy make a good faith effort to contact the prescriber.

Private Pay Agreement

- Network pharmacies and out-of-network pharmacies are prohibited from billing or collecting any amount from a Member for covered services (unless the Member requests pharmacy to accept cash payment for the prescription – see PL 18-008 below). The Member's MCOs informs their Members of their responsibility to pay the costs for non-covered services, and must require the network pharmacy to:
  1. Inform Members of costs for non-covered services prior to rendering such services; AND
  2. Obtain a signed private pay form from such Members. See link below or Appendix, p. vi, at the end of the handbook
- Microsoft Word - Private Pay Agreement (tmhp.com)

P-18-008: Cash Payments for Prescriptions

Below is the policy surrounding a pharmacy's ability to accept cash payments for Medicaid prescriptions when requested by the recipient:

1. Pharmacists always have the option to deny cash payments, if in their professional opinion, the prescription is for inappropriate use, including, but not limited to, inappropriate opioid uses.

2. If the client is a known Medicaid recipient, and the recipient requests that all or part of a prescription not be filled as a Medicaid benefit, then the prescription may be paid for in cash, either in part or in whole.

3. If the client is a known Medicaid recipient, and the recipient requests the pharmacy to fill only a portion of the prescription as a Medicaid benefit, then the remainder of the prescription may be paid for in cash.

4. This policy does not apply to people enrolled in the HHSC Inspector General Lock-In Program.

Provider Complaint Process to HHSC (Star and STAR Kids Members)

The Network Provider understands and agrees that HHSC reserves the right and retains the authority to make reasonable inquiry and to conduct investigation into Provider and Member Complaints.

- Initial point of contact is the Member's MCO and/or Navitus when related to pharmacy benefits.
- Pharmacy may contact the Navitus Texas Provider Hotline at 877-908-6023 to file a complaint. If after completing this process, the pharmacy believes they did not receive full due process from the respective MCO/Navitus, they may file a complaint or inquiry to hpm_complaints@hhsc.state.tx.us or mail to:

  Texas Health and Human Services Commission
  Provider Complaints
  Health Plan Operations, H-320
  P.O. BOX 85200
  Austin, TX. 78708

- For additional information, visit the Texas Administrative Code 1 TAC 353.[119]
- State Fair Hearing Information
- If a Member, as a member of the health plan, disagrees with the health plan's decision, the Member has the right to ask for a State Fair Hearing. The Member may name someone to represent him or her by writing a letter to the health plan telling the MCO the name of the

[119] http://texreg.sos.state.tx.us/public/readtac$ext.ViewTAC?tac_view=4&ti=1&pt=15&ch=353

person the Member wants to represent him or her. A provider may be the Member's representative. The Member or the Member's representative must ask for the fair hearing within 90 days of the date on the health plan's letter that tells of the decision being challenged. If the Member does not ask for the fair hearing within 90 days, the Member may lose his or her right to a fair hearing. To ask for a fair hearing, the Member or the Member's representative should either send a letter to the health plan at (address for health plan) or call (number for health plan).

- If the Member asks for a fair hearing within 10 days from the time the Member gets the hearing notice from the health plan, the Member has the right to keep getting any service the health plan denied, at least until the final hearing decision is made. If the Member does not request a fair hearing within 10 days from the time the Member gets the hearing notice, the service the health plan denied will be stopped.
- If the Member asks for a fair hearing, the Member will get a packet of information letting the Member know the date, time, and location of the hearing. Most fair hearings are held by telephone. At that time, the Member or the Member's representative can tell why the Member needs the service the health plan denied.
- HHSC will give the Member a final decision within 90 days from the date the Member asked for the hearing.

EXTERNAL MEDICAL REVIEW INFORMATION

- **Can a Member ask for an External Medical Review?**

If a Member, as a member of the health plan, disagrees with the health plan's internal appeal decision, the Member has the right to ask for an External Medical Review. An External Medical Review is an optional, extra step the Member can take to get the case reviewed for free before the State Fair Hearing. The Member may name someone to represent him or her by writing a letter to the health plan telling the MCO the name of the person the Member wants to represent him or her. A provider may be the Member's representative. The Member or the Member's representative must ask for the External Medical Review within 120 days of the date the health plan mails the letter with the internal appeal decision. If the Member does not ask for the External Medical Review within 120 days, the Member may lose his or her right to an External Medical Review. To ask for an External Medical Review, the Member or the Member's representative should either:

- Fill out the 'State Fair Hearing and External Medical Review Request Form' provided as an attachment to the Member Notice of MCO Internal Appeal Decision letter and mail or fax it to <MCO name> by using the address or fax number at the top of the form;
- Call the Member's MCO; or
- Email the Member's MCO>

If the Member asks for an External Medical Review within 10 days from the time the health plan mails the appeal decision, the Member has the right to keep getting any service the health plan denied, based on previously authorized services, at least until the final State Fair Hearing decision is made. If the Member does not request an External Medical Review within 10 days from the time the Member gets the appeal decision from the health plan, the service the health plan denied will be stopped.

The Member, the Member's authorized representative, or the Member's LAR may withdraw the Member's request for an External Medical Review before it is assigned to an Independent Review Organization or while the Independent Review Organization is reviewing the Member's External Medical Review request. The Member, the Member's authorized representative, or the Member's LAR must submit the request to withdraw the EMR using one of the following methods: (1) in writing, via United States mail, email, or fax; or (2) orally, by phone or in person. An Independent Review Organization is a third-party organization contracted by HHSC that conducts an External Medical Review during Member appeal processes related to Adverse Benefit Determinations based on functional necessity or medical necessity. An External Medical Review cannot be withdrawn if an Independent Review Organization has already completed the review and made a decision.

Once the External Medical Review decision is received, the Member has the right to withdraw the State Fair Hearing request. If the Member continues with the State Fair Hearing the Member can also request the Independent Review Organization to be present at the State Fair Hearing. The Member can make both of these requests by contacting the Member's MCO at (specify MCO information) or the HHSC Intake Team at EMR_Intake_Team@hhsc.state.tx.us.

If the Member continues with a State Fair Hearing and the State Fair Hearing decision is different from the Independent Review Organization decision, the State Fair Hearing decision is final. The State Fair Hearing decision can only uphold or increase Member benefits from the Independent Review Organization decision.

Can a Member ask for an emergency External Medical Review?

If a Member believes that waiting for a standard External Medical Review will seriously jeopardize the Member's life or health, or the Member's ability to attain, maintain, or regain maximum function, the Member or Member's representative may ask for an emergency External Medical Review and emergency State Fair Hearing by writing or calling the Member's MCO. To qualify for an emergency External Medical Review and emergency State Fair Hearing the Member must first complete the Member's MCO internal appeals process.

Provider Complaint Process to TDI (CHIP Members)

- CHIP Member complaints and appeals are subject to disposition consistent with the Texas Insurance Code and any applicable TDI regulations.
- Pharmacy may submit a complaint to Navitus regarding the pharmacy benefits/program for Medicaid or CHIP. The complaint may be made orally and/or in writing.
- Pharmacy may contact the Navitus Texas Provider Hotline at 877-908-6023 to file a complaint orally or written to:

  Navitus Health Solutions
  Attn: Appeals and Grievance Coordinator
  P.O. Box 999
  Appleton, WI 54912-0999

- If there is a disagreement with the decision or a preference to file a complaint with the Texas Department of Insurance (TDI), information can be found at:
  - Get help with an insurance complaint (texas.gov) or
  - for more information contact: ConsumerProtection@tdi.texas.gov

Provider Contract Checklist (HHSC Uniform Managed Care Manual)

- HHSC designed this checklist to help ensure that the MCOs develop their contracts with Network Providers consistent with HHSC requirements. These Standard Contract Provisions must be in writing and included in all Network Provider Contracts or the MCOs Provider Manual.
- The MCO is prohibited from imposing restrictions on Medicaid/CHIP pharmacy providers' enrollment in Medicaid/CHIP as a condition to enroll in other lines of business.
- The MCO is prohibited from implementing significant, non-negotiated, across-the-board provider reimbursement rate reduction unless prior approval has been obtained by HHSC.
- The MCO must ensure reasonable pharmacy provider reimbursement rates include a dispensing fee, administration fees (when applicable) and ingredient costs.
- The MCO must follow the requirements in applicable contracts regarding reimbursement for pharmacy providers.
- The MCO must ensure that pharmacy provider processes and procedures must be provided in a separate Texas Medicaid section specific to Medicaid and CHIP only.
- The MCO must ensure that provider contracts do not include language that permits:
  - pharmacy provider rate reductions without HHSC notification of approval as required under Section 8.1.4.8;
  - reconciliation methodologies that include Medicaid or CHIP claims;
  - mechanisms that facilitate "spread pricing," including pharmacy provider reimbursement clawbacks or discounts, which is described below in this section; or
  - PBM restrictions that are greater than those required by HHSC for Medicaid/CHIP participation.

- Unless directed by HHSC, the MCO and its PBM are prohibited from implementing an aggregate reconciliation process after the point-of-sale transaction such that the final cost of drugs for payors is changed or the price paid to pharmacy providers is changed. Such prohibition includes aggregate reconciliation processes for additional fees, contracted effective rate agreements, payment reductions, and the recoupments of funds based on financial performance measures. This prohibitive language does not apply to audit-related claim reviews, approved Alternative Payment Models, or Fraud, Waste, and Abuse investigations.
- The MCO must provide a Network pharmacy the sources used to determine the MAC pricing at contract execution, renewal, and upon request. MCOs may not use as a pricing source provider performance standards, provider network performance standards, or effective rate agreements.

Reporting Abuse, Neglect, or Exploitation (ANE)— MEDICAID MANAGED CARE

- **Report suspected Abuse, Neglect, and Exploitation:**
- MCOs and providers must report any allegation or suspicion of ANE that occurs within the delivery of long-term services and supports to the appropriate entity. The managed care contracts include MCO, and provider responsibilities related to identification and reporting of ANE. Additional state laws related to MCO, and provider requirements continue to apply. Report to the Health and Human Services (HHS) if the victim is an adult or child who resides in or receives services from: • Nursing facilities; • Assisted living facilities; • Home and Community Support Services Agencies (HCSSAs) – Providers are required to report allegations of ANE to both DFPS and HHS; • Adult day care centers; or • Licensed adult foster care providers Contact HHS at 1-800-458-9858. For additional information refer to the link: https://hhs.texas.gov/abouthhs/yourrights/complaint-incident-intake/how-can-i-report-abuse-neglect-or-exploitation . MCOs and providers must report any allegation or suspicion of ANE to the appropriate entity. The managed care contracts include MCO, and provider responsibilities related to identification and reporting of ANE. The Medicaid/CHIP Division at the Texas Health and Human Services Commission developed this document in order to assist MCOs and providers with reporting ANE. Additional state laws related to MCO, and provider requirements continue to apply.

- **Report to the Department of Family and Protective Services (DFPS) if the victim is one of the following:**
  - An adult who is elderly or has a disability, receiving services from:
    - Home and Community Support Services Agencies (HCSSAs) – also required to report any HCSSA allegation to HHS;
    - Unlicensed adult foster care provider with three or fewer beds
  - An adult with a disability or child residing in or receiving services from one of the following providers or their contractors:

- Local Intellectual and Developmental Disability Authority (LIDDA), Local mental health authority (LMHAs), Community center, or Mental health facility operated by the Department of State Health Services;
- a person who contracts with a Medicaid managed care organization to provide behavioral health services;
- a managed care organization;
- an officer, employee, agent, contractor, or subcontractor of a person or entity listed above; and

➢ An adult with a disability receiving services through the Consumer Directed Services option
➢ Contact DFPS at 1-800-252-5400 or, in non-emergency situations, online at Welcome (txabusehotline.org)

- **Report to Local Law Enforcement:**
  - ➢ If a provider is unable to identify State agency jurisdiction but an instance of ANE appears to have occurred, report to a local Law enforcement agency and DFPS.

- **Failure to Report or False Reporting:**
  - ➢ It is a criminal offense if a person fails to report suspected ANE of a person to DFPS, DADS, or a Law enforcement agency[120]
  - ➢ It is a criminal offense to report false information knowingly or intentionally to DFPS, DADS, or a Law enforcement agency regarding ANE [121]
  - ➢ Everyone has an obligation to report suspected ANE against a child, an adult that is elderly, or an adult with a disability to DFPS. This includes ANE committed by Member's family, DFPS licensed foster parent or accredited child placing agency foster home, DFPS licensed general residential operation, or at a childcare center.

Timely Filing Limits

- Points-of-sale (POS) claims are generally submitted at the time of dispensing. However, there may be mitigating reasons that require a claim to be submitted after being dispensed. Transmission of claims using the current date for a past service date is a violation of program policy and could result in an audit exception.

  Exception:
  Claims that exceed the prescribed timely filing limit will deny with NCPDP Error 81, "Claim Too Old by x days." The exception to this is claims for Members that have been certified

[120] Texas Human Resources Code, Section 48.052; Texas Health & Safety Code, Section 260A.012; and Texas Family Code, Section 261.109
[121] Texas Human Resources Code, Sec. 48.052; Texas Health & Safety Code, Section 260A.013; and Texas Family Code, Section 261.107

with retroactive Medicaid eligibility. These claims will process online for 95 days after the certification date of retroactive eligibility regardless of the date of service.

Verification--Verifying Member Medicaid Eligibility

- Each person approved for Medicaid benefits gets a *Your Texas Benefits* Medicaid card. However, having a card does not always mean the patient has current Medicaid coverage. You must still verify eligibility. There are several ways to do this:
  - Swipe the patient's *Your Texas Benefits* Medicaid card through a standard magnetic card reader, if your office uses that technology.
  - Search for the patient using a secure website with a variety of useful features for Medicaid providers.
  - Use TexMedConnect on the TMHP website at Welcome Texas Medicaid Providers | TMHP.
  - Call the Your Texas Benefits provider helpline at 1-855-827-3747.
  - Call Provider Services at the patient's medical or dental plan.

- Important: Do not send patients who forgot or lost their cards to an HHSC benefits office for a paper form. They can request a new card by calling 1-855-827-3748. Medicaid Members also can go online to order new cards or print temporary cards. For instructions, visit Your Texas Benefits - Learn and click Learn more about the Your Texas Benefits Medicaid card.

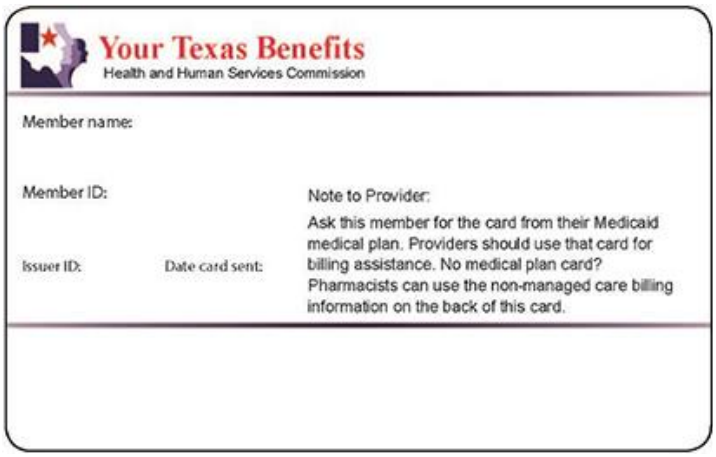
Members will also be provided a medical ID card from their Managed Care Organization (MCO). You may contact the number on the back of this card for questions or to verify eligibility. Member ID cards will vary depending on MCO.

Your Texas Benefits Medicaid Card

Medicaid Card Questions & Answers | Texas Health and Human Services

- Provider Interactive Voice Response guide (IVR)-- Provider IVR User Guide (txhealthsteps.com)
- *Your Texas* Medicaid & CHIP Members | Texas Health and Human Services
- http://www.tmhp.com/TMHP_File_Library/Medicaid/Your%20Texas%20Benefits.pdf
- CHIP into TIERS (effective 9/1/2013) -
  - Microsoft Word - 6.03_CHIP Cost Sharing_V2.1_FINAL (texas.gov)
  - CHIP and CHIP Perinate Eligibility –
    CHIP Program Members have eligibility for 12-months.
    - CHIP Perinatal FAQs | Texas Health and Human Services
  - Medicaid & CHIP | Texas Health and Human Services

Sample ID Card



Websites

- Navitus Texas Managed Care Medicaid Payors
  - Community First Health Plan…Community First Health Plans | Your Local Health Plan
  - Community Health Choice……. Community Cares - Community Health Choice
  - Cook Children's Health Plan. Cook Children's Health Care System (cookchildrens.org)
  - Dell Children's Health Plan/Seton….. CHIP and STAR Health Insurance - Dell Children's Health Plan (dellchildrens.net)
  - Driscoll Children's Health Plan…….. Driscoll Health Plan
  - El Paso Health…….. Medicaid, CHIP, Group Health Insurance. (elpasohealth.com)
  - FirstCare Health Plan…….. FirstCare - Health Plans by Texans for Texans
  - Parkland Community Health Plan…….. Medicaid and CHIP Plans for Dallas Service Area | Parkland Community Health Plan (parklandhealthplan.com)
  - Scott and White Health Plan…….. RightCare Home (swhp.org)
  - Texas Children's Health Plan. Texas Children's Health Plan (texaschildrenshealthplan.org)

- Resources
  - Texas Vendor Drug Program… Homepage | Vendor Drug Program (txvendordrug.com)
  - Preferred Drug List (PDL). Preferred Drugs | Vendor Drug Program (txvendordrug.com)
  - Formulary…….. Formulary | Vendor Drug Program (txvendordrug.com)
  - Texas Medicaid… Welcome Texas Medicaid Providers | TMHP
  - HHSC…… Texas Health and Human Services | Texas Health and Human Services
  - Epocrates (TX Medicaid and CHIP Formulary & PDL) Point of care medical application | Epocrates

Utah

- AUDIT LAWS/REGULATIONS
  C58-17b-S622_1800010118000101.pdf (utah.gov)
- BOARD OF PHARMACY
  DOPL - Pharmacy (utah.gov)
- PHARMACY LAWS/REGULATIONS
  DOPL – Pharmacy-Laws and Rules (utah.gov)

Vermont

- AUDIT LAWS/REGULATIONS
  Vermont Laws
- BOARD OF PHARMACY
  Vermont Secretary of State - Office of Professional Regulation Pharmacy Section
- PHARMACY LAWS/REGULATIONS
  Pharmacy Statutes, Rules & Resources (vermont.gov)

Virginia

- AUDIT LAWS/REGULATIONS
  Code of Virginia Code - Article 9. Pharmacy Benefits Managers
- BOARD OF PHARMACY
  Virginia Board of Pharmacy - Home
- PHARMACY LAWS/REGULATIONS
  Virginia Board of Pharmacy - Laws & Regulations

Washington

- AUDIT LAWS/REGULATIONS
  Chapter 19.340 RCW: pharmacy benefit managers (wa.gov)
- BOARD OF PHARMACY
  Pharmacy Professions Licensing Information :: Washington State Department of Health
- PHARMACY LAWS/REGULATIONS
  Pharmacy Laws: Washington State Department of Health

West Virginia

- AUDIT LAWS AND REGULATIONS
  West Virginia Code (wvlegislature.gov)
- BOARD OF PHARMACY
  Home - WV Board of Pharmacy (wvbop.com)
- PHARMACY LAWS/REGULATIONS
  Pharmacy Law and Rules - WV Board of Pharmacy (wvbop.com)

Wisconsin

- AUDIT LAWS AND REGULATIONS
  Wisconsin Legislature: 2021 Wisconsin Act 9
- BOARD OF PHARMACY
  DSPS Pharmacy Examining Board (wi.gov)
- PHARMACY LAWS/REGULATIONS
  DSPS Pharmacy Examining Board (wi.gov)

Under Wisconsin Act 9[122] (SB 3), for certain applicable plans, a member that has an adverse reaction to the generic prescription drug or the prescription that is being substituted for an originally prescribed prescription drug, a pharmacist may fill one 30-day supply of the originally prescribe drug at the cost-sharing amount that applies to the drug at the time of substitution.
To process such a claim, a pharmacy should enter:

- an override using DAW 3 and
- a DUR conflict code of AR

Wyoming

- AUDIT LAWS AND REGULATIONS
  Pharmacy benefit manager audits, Wyo. Stat. § 26-52-103
- BOARD OF PHARMACY
  Pharmacy (wyo.gov)
- PHARMACY LAWS/REGULATIONS
  Pharmacy - Laws (wyo.gov)

[122] SB3

ARKANSAS STATE ADDENDUM
TO THE NAVITUS PARTICIPATING PHARMACY AGREEMENT

This Arkansas Addendum ("Addendum") applies to the extent that Participating Pharmacy dispenses outpatient prescriptions and drug products and provides pharmaceutical services to Members. All definitions used in this Addendum, which are not otherwise defined, have the meanings assigned to them in the Participating Pharmacy Agreement ("Agreement"), which Navitus and Participating Pharmacy previously executed. Both parties desire for the Agreement and the services provided thereunder to comply with all applicable Laws and regulations. This Addendum is intended to clarify the parties' responsibilities under the Laws of the State of Arkansas.

Now therefore, Navitus and Participating Pharmacy agree as follows:

1. Effectiveness of Addendum. If any provision of this Addendum conflicts with the terms or definitions of the Agreement, the terms of this Addendum will control with respect to Payors subject to Arkansas Law or regulation. To the extent that Participating Pharmacy provides Covered Pharmacy Services to Members of Payors licensed under Arkansas Law, Participating Pharmacy agrees to comply with any requirements for participation as a Participating Pharmacy in Arkansas as required by applicable Law. The terms of this Addendum will apply solely with regard to Covered Pharmacy Services provided to Members of Payors licensed as a health carrier under Arkansas Law and will not be deemed to amend the terms of the Agreement for Payors licensed in other states as a health carrier or for Covered Pharmacy Services not otherwise under the jurisdiction of the State of Arkansas, which may be covered by the requirements of other states. In the event of a conflict between the terms set forth in this Addendum and the terms set forth in the Agreement this Addendum shall control for Covered Pharmacy Services.

2. To the extent Participating Pharmacy provides Covered Pharmacy Services to Members of a health maintenance organization:

(a) In the event the health maintenance organization fails to pay for healthcare services as set forth in the Agreement, Member shall not be liable to the provider for any sums owed by the health maintenance organization. (Ark. Code Ann. § 23-76-119(c)(1))

(b) Participating Pharmacy shall not maintain an action at law against a subscriber or enrollee to collect sums owed to them by the health maintenance organization nor shall they make any statement, either written or oral, to any subscriber or enrollee that makes demand for, or would lead a reasonable person to believe that a demand is being made for, payment of any amounts owed by the health maintenance organization. (Ark. Code Ann. § 23-76-119(c)(3)(A))

3. Medical Necessity. To the extent Participating Pharmacy provides Covered Pharmacy Services to Members of an insurer under a minimum basic benefit policy issued under Chapter 98 of the Arkansas Code Annotated, the Member will have no obligation to make payment for any Covered Pharmacy Service rendered by Participating Pharmacy that is determined not to be medically necessary. However, charges for medically necessary services received by the Member which are not covered by the minimum basic benefit policy shall be considered the responsibility of the Member.

4. Gag Clauses Prohibited. Participating Pharmacy may not prohibit, restrict, or penalize in any way disclosure to Member any healthcare information that Participating Pharmacy deems appropriate regarding the nature of treatment, risks, or alternatives thereto, the availability of alternate therapies, consultations, or tests, the decision of utilization reviewers or similar persons to authorize or deny services, the process that is used to authorize or deny healthcare services or benefits, or information on financial incentives and structures used by the insurer. (Ark. Code Ann. §§ 23-99-407, 23-92-507)

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5. Continuity of Care. To the extent Participating Pharmacy provides Covered Pharmacy Services to Members of a health insurer pursuant to applicable Arkansas insurance law, in the event the Agreement is terminated, pharmacy agrees to continue to provide Covered Pharmacy Services to Members as an in-network benefit until a current episode of treatment for an acute condition is completed or until the end of ninety (90) days, whichever occurs first. During such period of time, pharmacy shall be deemed to be a Participating Pharmacy for purposes of reimbursement, utilization management, and quality of care. (Ark. Code Ann. § 23-99-408)

6. Payment Retroactivity. Pursuant to Ark. Code Ann. § 23-92-506(c), a claim or aggregate of claims for Covered Pharmacy Services shall not be directly or indirectly retroactively denied or reduced after adjudication of the claim or aggregate of claims unless:

(a) The original claim was submitted fraudulently;
(b) The original claim payment was incorrect because the pharmacy or pharmacist had already been paid for the pharmacist services; or
(c) The pharmacist services were not properly rendered by the pharmacy or pharmacist.

7. Reimbursements. To the extent Participating Pharmacy provides Covered Pharmacy to health benefit plans as defined in Ark. Code Ann. § 23-92- 503(2) and healthcare payors as defined in Ark. Code Ann. § 23-92-503(3), the following requirements shall apply pursuant to Arkansas' Emergency Rule 128 and Ark. Code Ann. § 23-92-506(a)(1):

(a) The Arkansas Insurance Commissioner ("Commissioner") may review and approve the compensation program Navitus from a health benefit plan to ensure that the reimbursement for Covered Pharmacy Services paid to Participating Pharmacy or a pharmacist is fair and reasonable to provide an adequate pharmacy benefits manager network for a health benefit plan.

(b) Navitus shall include a fair and reasonable cost to dispense to Participating Pharmacies in its administration of drug benefits under its health benefit plan.

(i) A fair and reasonable cost to dispense shall be calculated commiserate with the time, labor, supplies, and other administrative costs associated with the dispensing of the drug by the pharmacy.

(ii) This cost to dispense shall be uniform or equally applied to all Participating Pharmacies servicing the health benefit plan. In administrating drug benefits for health benefit plans, Navitus shall not recoup or recover any increased costs to dispense from a subscriber at the point of sale through increased cost-sharing requirement ratios or percentages (co-insurance, co-payment, or deductibles) on the Member.

(iii) For the first calendar year for 2025, every health insurer shall file with the Commissioner, no later than by November 30, 2024, a written report describing each healthcare payor's calculation amount, and methodology for such calculation, of the cost to dispense as required by this Rule. This requirement shall apply to plan year 2025 and thereafter, for each succeeding plan year after 2025, a health insurer shall submit such report on or before March 1 to apply for that next plan year. All data and materials submitted for such reports shall be deemed confidential, proprietary and not subject to the Arkansas Freedom of Information Act.

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8. Pursuant to Ark. Code Ann. § 23-92-506(b), Navitus shall not:
   (a) unless reviewed and approved by the Commissioner, charge a pharmacist or pharmacy a fee related to the adjudication of a claim, including without limitation a fee for:
      (i) The receipt and processing of a pharmacy claim;
      (ii) The development or management of claims processing services in a pharmacy benefits manager network; or
      (iii) Participation in a pharmacy benefits manager network;
   (b) unless reviewed and approved by the Commissioner in coordination with the Arkansas State Board of Pharmacy, require pharmacy accreditation standards or certification requirements inconsistent with, more stringent than, or in addition to requirements of the board.

9. Anti-Clawback. Pursuant to Ark. Code Ann. § 4-88-1004, a Member shall not be required to make a payment for Covered Pharmacy Services in an amount greater than the pharmacist or Participating Pharmacy providing the pharmacists services may retain from all payment sources.

10. MAC Lists.
   (a) Navitus shall provide access to its Maximum Allowable Cost List to each pharmacy subject to the Maximum Allowable Cost List;
   (b) Update its Maximum Allowable Cost List on a timely basis, but in no event longer than seven (7) calendar days from an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in the state or a change in the methodology on which the Maximum Allowable Cost List is based or in the value of a variable involved in the methodology;
   (c) Provide a process for each pharmacy subject to the Maximum Allowable Cost List to receive prompt notification of an update to the Maximum Allowable Cost List; and
   (d) Provide a reasonable administrative appeal procedure to allow pharmacies to challenge Maximum Allowable Cost List and reimbursements made under a Maximum Allowable Cost List for a specific drug or drugs as:
      (i) Not meeting the requirements of this section; or
      (ii) Being below the pharmacy acquisition cost.

   (e) The reasonable administrative appeal procedure shall include the following:
      (i) A dedicated telephone number, email address, and website for the purpose of submitting administrative appeals;
      (ii) The ability to submit an administrative appeal directly to the pharmacy benefits manager regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization; and
      (iii) No less than thirty (30) business days to file an administrative appeal.

   (f) Navitus shall respond to the MAC list challenge to an administrative appeal within thirty (30) business days after receipt of the challenge.

   (g) If a challenge to MAC list is made to an administrative appeal, Navitus shall within thirty (30) business days after receipt of the challenge either:

      (i) If the appeal is upheld:
         (1) Make the change in the maximum allowable cost list payment to at least the pharmacy acquisition cost;
         (2) Permit the challenging pharmacy or pharmacist to reverse and rebill the claim i question;

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(3) Provide the National Drug Code that the increase or change is based on to the pharmacy or pharmacist; and
(4) Make the change effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List;

(ii) If the appeal is denied, provide the challenging pharmacy or pharmacist the National Drug Code and the name of the national or regional pharmaceutical wholesalers operating in Arkansas that have the drug currently in stock at a price below the maximum allowable cost as listed on the Maximum Allowable Cost List; or

(iii) If the National Drug Code provided by the pharmacy benefits manager is not available below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale, then the pharmacy benefits manager shall adjust the maximum allowable cost as listed on the Maximum Allowable Cost List above the challenging pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.

(h) Navitus shall not reimburse Participating Pharmacy or pharmacist in Arkansas an amount less than the amount that Navitus reimburses a Navitus affiliate for providing the same pharmacist services. The amount shall be calculated on a per unit basis based on the same generic product identifier or generic code number.

(i) Participating Pharmacy or pharmacist may decline to provide the Covered Pharmacy Services to a Member or Navitus if, as a result of a Maximum Allowable Cost List, a Participating Pharmacy or pharmacist is to be paid less than the pharmacy acquisition cost of the Participating Pharmacy providing pharmacist services.

(j) This Section 8 does not apply to a Maximum Allowable Cost List maintained by the Arkansas Medicaid Program or the Employee Benefits Division.

(k) This Section 8 shall apply to the pharmacy benefits manager employed by the Arkansas Medicaid Program or the division if, at any time, the Arkansas Medicaid Program or the division engages the services of a pharmacy benefits manager to maintain a Maximum Allowable Cost List.

11. Arkansas Audit Bill of Rights. Pursuant to the Arkansas Pharmacy Audit Bill of Rights (A.C.A. § 17-92-1201(b)) and notwithstanding any other law, when an audit of the records of Participating Pharmacy is conducted by a Navitus, the audit shall be conducted in accordance with the following bill of rights:

(a) For the initial on-site audit, Navitus shall give Participating Pharmacy notice at least one (1) week before conducting the initial on-site audit for each audit cycle;

(b) Any audit that involves clinical or professional judgment shall be conducted by or in consultation with a pharmacist;

(c) Any clerical or recordkeeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document or record shall not in and of itself constitute fraud. However,

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such a claim may be subject to recoupment and is not subject to criminal penalties without proof of intent to commit fraud;

(d) Participating Pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;

(e) A finding of an overpayment or underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs. However, recoupment of such foregoing claims shall be based on the actual overpayment unless the projection for overpayment or underpayment is part of a settlement by the pharmacy;

(f) (i) Where an audit is for a specifically identified problem that has been disclosed to Participating Pharmacy, the audit shall be limited to claims that are identified by prescription number.
(ii) For an audit other than described in subdivision 6(f)(i) of this section, an audit shall be limited to twenty-five (25) prescriptions that have been randomly selected.
(iii) If an audit reveals the necessity for a review of additional claims, the audit shall be conducted on site.
(iv) Except for audits initiated under subdivision 6(f)(i) of this section, Navitus shall not initiate an audit of Participating Pharmacy more than two (2) times in a calendar year.

(g) A recoupment shall not be based on:
(i) Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the Arkansas State Board of Pharmacy; or

(ii) A requirement that Participating Pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the Arkansas State Board of Pharmacy.

(iii) This applies only to audits of claims submitted for payment on or after January 1, 2012.

(iv) Subdivisions 6(g)(i) and (ii) of this section do not apply in cases of United States Food and Drug Administration regulation or drug manufacturer safety programs;

(h) Recoupment shall only occur following the correction of a claim and shall be limited to amounts paid in excess of amounts payable under the corrected claim;

(i) Except for Medicare claims, approval of drug, prescriber, or patient eligibility upon adjudication of a claim shall not be reversed unless Participating Pharmacy or pharmacist obtained the adjudication by fraud or misrepresentation of claim elements;

(j) Each Participating Pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity;

(k) Participating Pharmacy shall be allowed at least thirty (30) days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit;

(l) The period covered by an audit shall not exceed twenty-four (24) months from the date the claim was submitted to or adjudicated by Navitus;

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(m) Unless otherwise consented to by Participating Pharmacy, an audit shall not be initiated or scheduled during the first seven (7) calendar days of any month due to the high volume of prescriptions filled during that time;

(n) The preliminary audit report shall be delivered to Participating Pharmacy within one hundred twenty (120) days after conclusion of the audit. A final audit report shall be delivered to Participating Pharmacy within six (6) months after receipt of the preliminary audit report or the final appeal, whichever is later; and

(o) Notwithstanding any other provision in this subsection, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.

12. Recoupments. Pursuant to A.C.A. § 17-92-1201(c), recoupments of any disputed funds shall only occur after final internal disposition of the audit, including the appeals process as set forth below.

13. Appeals of Audits. Pursuant to A.C.A. § 17-92-1201(d), Navitus shall establish an appeals process under which Participating Pharmacy may appeal an unfavorable preliminary audit report to the entity. If, following the appeal, Navitus finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, Navitus shall dismiss the audit report or the unsubstantiated portion of the audit report without any further proceedings.

14. Final Audit Report. Navitus shall provide a copy of the final audit report to Payor after completion of any review process.

15. Audit Charge.

(a) The full amount of any recoupment on an audit shall be refunded to the responsible party.

(b) Except as provided in subdivision 10(c) of this section, a charge or assessment for an audit shall not be based, directly or indirectly, on amounts recouped.

(c) Subdivision 10(b) of this section does not prevent Navitus from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both the following conditions are met:
  (i) The responsible party and Navitus have a contract that explicitly states the percentage charge or assessment to the responsible party; and
  (ii) A commission or other payment to an agent or employee of Navitus is not based, directly or indirectly on amounts recouped.

16. Fraud. The Arkansas Pharmacy Audit Bill of Rights requirements under A.C.A. § 17-92-1201 and as set forth in this Addendum do not apply to any audit, review, or investigation that involves alleged fraud, willful misrepresentation, or abuse, including without limitation:

(a) Medicaid fraud as defined in A.C.A. § 5-55-111;
(b) Abuse or fraud as defined in A.C.A. § 20-77-1702; or
(c) Insurance fraud.

This Addendum constitutes the entire and complete understanding between the parties regarding the subject matter hereof and supersedes all previous discussions, representations, proposals, offers, counteroffers, and writings between the parties that may have occurred before entering into this Addendum.

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In the event that any statute referenced herein is amended, superseded, or otherwise modified by legislative or regulatory action of the State of Arkansas, such modified or successor statute shall govern and control to the fullest extent permitted by law.

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COLORADO STATE ADDENDUM
TO THE PARTICIPATING PHARMACY AGREEMENT

Navitus and Participating Pharmacy have executed a Participating Pharmacy Agreement (the "Agreement") pursuant the Participating Pharmacy Agreement (collectively the "Agreement") to which Participating Pharmacy agreed to dispense outpatient prescriptions and drug products and to provide pharmaceutical services to Members. All definitions used in this Addendum, which are not otherwise defined, have the meanings assigned to them in the Agreement. Both parties desire for the Agreement and the services provided thereunder to comply with all applicable Laws and regulations of the State of Colorado to the extent that Participating Pharmacy provides Covered Pharmacy Services to Members of Payors licensed under Colorado Law. This Addendum is intended to clarify the parties' responsibilities and provide firm compliance under the Laws of the State of Colorado.

Now therefore, Navitus and Participating Pharmacy agree as follows:

1. Effectiveness of Addendum. If any provision of this Addendum conflicts with the terms or definitions of the Agreement, the terms of this Addendum will control with respect to Payors subject to Colorado Law or regulation. To the extent that Participating Pharmacy provides Covered Pharmacy Services to Members of Payors licensed under Colorado Law, Participating Pharmacy agrees to comply with any requirements for participation as a Participating Pharmacy in Colorado as required by applicable Law. The terms of this Addendum will apply solely with regard to Covered Pharmacy Services provided to Members of Payors licensed as a health carrier under Colorado Law and will not be deemed to amend the terms of the Agreement for Payors licensed in other states as a health carrier or for Covered Pharmacy Services not otherwise under the jurisdiction of the State of Colorado, which may be covered by the requirements of other states. In the event of a conflict between the terms set forth in this Addendum and the terms set forth in the Agreement, this Addendum shall control for Covered Pharmacy Services.

2. Retroactive Reduction of Claims. Pursuant to Colorado Revised Statutes Annotated (C.R.S.A.) § 10-16-122.3, once Navitus receives a clean claim submitted by Participating Pharmacy, Navitus cannot retroactively decrease payment on the claim post-sale, except through an audit conducted under C.R.S.A. § 10-16-122.5. However, Navitus can retroactively increase payment pursuant to a written agreement between Navitus and Participating Pharmacy or for rectifying clerical errors. Participating Pharmacy shall conduct annual audits on Navitus to monitor and verify adherence with the foregoing requirements of this Section 2.

3. MAC Pricing. Pursuant to C.S.R.A. § 10-16-122.6 (1), Participating Pharmacy shall have the right to request the right to obtain, within ten (10) days after the request, a current list of sources used in determining Maximum Allowable Cost pricing. Navitus will update pricing information at least every seven (7) days and

provide a method for Participating Pharmacies to promptly review pricing updates. Participating Provider is mandated to conduct annual audits on Navitus to verify adherence to this addendum.

4. MAC Appeals. Pursuant to C.R.S.A § 10-16-122.6 (3), Navitus will provide a process to appeal, investigate, and resolve disputes regarding Maximum Allowable Cost pricing, which includes:
   a. A twenty-one-day (21) limit on the right to appeal following the initial claim;
   b. A requirement that the appeal be investigated and resolved within twenty-one (21) days after the appeal;
   c. A telephone number at which the Participating Pharmacy may contact Navitus to speak to a person responsible for processing appeals;
   d. A requirement that Navitus provide a reason for any appeal denial and the identification of the national drug code of a drug that may be purchased by the Participating Pharmacy at a price at or below the benchmark price as determined by Navitus; and
   e. A requirement that Navitus make an adjustment to a date no later than one (1) day after the date of determination. This requirement does not prohibit Navitus from retroactively adjusting a claim for the appealing pharmacy or for another similarly situated pharmacy.

5. 340B. The Agreement shall not, under any circumstances, (i) restrict or limit the dispensing of 340B drugs to any eligible entities or their contract pharmacies; (ii) restrict or limit access for a member based solely on the member's 340B status; or (iii) impose any restriction or limitation on a member related to the member's participation in the 340B program.

6. Specialty Pharmacy Payor Network Restriction. Where applicable to a Specialty Pharmacy Addendum to the Agreement, Participating Pharmacy expressly acknowledges and agrees that Navitus shall have sole and absolute discretion to restrict, limit, or exclude Participating Pharmacy's participation, including any of its Specialty Pharmacy Locations and/or pharmacy affiliations, in any Specialty Pharmacy Network, whether on a Payor-by-Payor basis or otherwise. Such restrictions may include, but are not limited to, limitations based on state, geographical region, specific pharmacy location, NCPDP number, or any other criteria as determined by Navitus or Payor in their sole discretion, subject only to applicable Law. For avoidance of doubt, Navitus has no obligation whatsoever to include any particular Participating Pharmacy Location in any state or geographical region, regardless of Participating Pharmacy's existing locations or operations, nor any obligation to include any NCPDP affiliations of Participating Pharmacy in any network. Navitus reserves the right to exclude and restrict the participation of Participating Pharmacy Locations as described in this Section 6 of this Addendum. If Participating Pharmacy does not have Specialty Pharmacy Addendum this section is not applicable.

This Addendum constitutes the entire and complete understanding between the parties regarding the subject matter hereof and supersede all previous discussions, representations, proposals, offers, counteroffers, and writings between the parties that may have occurred before entering into this Addendum.

In the event that any statute referenced herein is amended, superseded, or otherwise modified by legislative or regulatory action by the State of Colorado, such modified or successor statute shall govern and control to the fullest extent permitted by law.

FLORIDA STATE ADDENDUM
TO THE NAVITUS PARTICIPATING PHARMACY AGREEMENT

This Florida Addendum ("Addendum") applies to the extent that Participating Pharmacy dispenses outpatient prescriptions and drug products and provides pharmaceutical services to Members of a pharmacy benefits plan or program subject to Florida law. All definitions used in this Addendum, which are not otherwise defined, have the meanings assigned to them in the Participating Pharmacy Agreement ("Agreement"), which Navitus and Participating Pharmacy previously executed. Both parties desire for the Agreement and the services provided thereunder to comply with all applicable Laws and regulations. This Addendum is intended to clarify the parties' responsibilities under the Laws of the State of Florida.

Now therefore, Navitus and Participating Pharmacy agree as follows:

1. Effectiveness of Addendum. If any provision of this Addendum conflicts with the terms or definitions of the Agreement, the terms of this Addendum will control with respect to Payors subject to Florida Law or regulation. To the extent that Participating Pharmacy provides Covered Pharmacy Services to Members of Payors licensed under Florida Law, Participating Pharmacy agrees to comply with any requirements for participation as a Participating Pharmacy in Florida as required by applicable Law. The terms of this Addendum will apply solely with regard to Covered Pharmacy Services provided to Members of Payors licensed as a health carrier under Florida Law and will not be deemed to amend the terms of the Agreement for Payors licensed in other states as a health carrier or for Covered Pharmacy Services not otherwise under the jurisdiction of the State of Florida, which may be covered by the requirements of other states. In the event of a conflict between the terms set forth in this Addendum and the terms set forth in the Agreement this Addendum shall control for Covered Pharmacy Services.

2. Definitions. The following state-specific definitions shall apply for purposes of this Addendum only (The NCPDP state code for the State of Florida is "57"):

a. "Brand Name or Generic Effective Rate" means the contractual rate set forth by a pharmacy benefit manager for the reimbursement of covered brand name or generic drugs, calculated using the total payments in the aggregate, by drug type, during the performance period. The effective rates are typically calculated as a discount from industry benchmarks, such as average wholesale price or wholesale acquisition cost.

b. "Incentive Payment(s)" means a retrospective monetary payment made as a reward or recognition by the pharmacy benefits plan or program or pharmacy benefit manager to a pharmacy for meeting or exceeding predefined pharmacy performance metrics as related to quality measures, such as Healthcare Effectiveness Data and Information Set measures.

c. "Maximum Allowable Cost Appeal Pricing Adjustment" means a retrospective positive payment adjustment made to a pharmacy by the pharmacy benefits plan or program or by the pharmacy benefit manager pursuant to an approved maximum allowable cost appeal request submitted by the same pharmacy to dispute the amount reimbursed for a drug based on the pharmacy benefit manager's listed maximum allowable cost price.

d. "Network Reconciliation Offsets" means a process during annual payment reconciliation between a pharmacy benefit manager and a pharmacy which allows the pharmacy benefit manager to

offset an amount for overperformance or underperformance of contractual guarantees across guaranteed line items, channels, networks, or payors, as applicable.

e. "Dispensing Fee" means a fee intended to cover reasonable costs associated with providing the drug to a covered person. This cost includes the pharmacist's services and the overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.

f. "Maximum Allowable Cost" or "MAC" means the per-unit amount that Navitus reimburses a pharmacy for a prescription drug, excluding dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges, if any.

3. Services. The following state specific provision shall apply for purposes of this Addendum only:

a. Upon Participating Pharmacy request, Navitus will provide a list of pharmacy benefits plans or programs in which the Participating Pharmacy is a part of the network. Updates to the list will be communicated to the Participating Pharmacy within 7 days. Navitus will not restrict the Participating Pharmacy or pharmacist from disclosing this information to the public.

b. Participating Pharmacy shall have no right to dispense quantities of Covered Products to Members in excess of Days Supply as limited by the applicable Plan Specifications or an executed applicable network addendum to this Agreement, except as permitted by applicable Law. Unless otherwise prohibited by Law, nothing in this Addendum is intended, or shall be construed, to prohibit a Participating Pharmacy or pharmacist from (a) offering mail or delivery services on an opt-in bases at the sole discretion of the Member; (b) mailing or delivering a Prescription Drug to a Member upon the Member's request; or (c) charging a shipping or handling fee to a Member requesting a Prescription Drug be mailed or delivered if the Participating Pharmacy or pharmacist discloses to the Member before the mailing or delivery the amount of the fee that will be charged and that the fee may not be reimbursable under the Member's Plan Specifications.

4. Payment. The following state-specific provisions shall apply for purposes of this Addendum only:

a. Navitus will not charge, withhold, or recoup direct or indirect remuneration fees, dispensing fees, brand name or generic effective rate adjustments through reconciliation, or any other monetary charge, withholding, or recoupments as related to discounts, multiple Network Reconciliation Offsets, adjudication transaction fees, and any other instance when a fee may be recouped from a pharmacy. The foregoing sentence does not or shall not apply to: (a) any Incentive Payments provided by Navitus to a Participating Pharmacy for meeting or exceeding predefined quality measures, such as Healthcare Effectiveness Data and Information Set measures; recoupment due to an erroneous claim, fraud, waste, or abuse; a claim adjudicated in error; a Maximum Allowable Cost Appeal Pricing Adjustment; or an adjustment made as part of a pharmacy audit pursuant to Florida Law; or (b) any recoupment that is returned to Florida for programs in Chapter 409 or the state group insurance program in § 110.123 of Florida Statutes Annotated.

b. At the time of adjudication for electronic claims or the time of reimbursement for nonelectronic claims, Navitus shall provide the Participating Pharmacy with a remittance, including such detailed information as is necessary for the Participating Pharmacy or pharmacist to identify the reimbursement schedule for the specific network applicable to the claim and which is the basis used by Navitus to calculate the amount of reimbursement paid. This information must include, but is not limited to, the applicable network reimbursement ID or plan ID as defined in the most

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current version of the NCPDP Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide.

c. Navitus shall communicate to Participating Pharmacy any basis of reimbursement information in accordance with the NCPDP Telecommunication Standard Implementation Guide, or its nationally recognized successor industry guide, when performing reconciliation for any effective rate guarantee, and that such basis of reimbursement information communicated is accurate, corresponds with the applicable network rate, and may be relied upon by the pharmacy.

5. Appeals. The following state-specific provisions shall apply for purposes of this Addendum only:

a. MAC Pricing Appeals. For disputes regarding MAC pricing under this Agreement the following applies:

(1) Navitus will provide a reasonable administrative appeal procedure to allow a Participating Pharmacy or pharmacist to challenge the maximum allowable cost pricing information and the reimbursement made under the maximum allowable cost as defined in § 627.64741 of Florida Statutes Annotated for a specific drug as being below the acquisition cost available to the challenging Participating Pharmacy or pharmacist.

(2) The administrative appeal procedure will include a telephone number and e-mail address, or a website, for the purpose of submitting the administrative appeal. The appeal may be submitted by the Participating Pharmacy or its agent directly to Navitus or through a pharmacy service administration organization. Participating Pharmacy or pharmacist has at least 30 business days after a MAC update or after an adjudication for an electronic claim or reimbursement for a nonelectronic claim to file the administrative appeal.

(3) Navitus will respond to the administrative appeal within 30 business days after receipt of the appeal.

(4) If the appeal is upheld, Navitus will: (i) update the maximum allowable cost pricing information to at least the acquisition cost available to the pharmacy; (ii) permit the pharmacy or pharmacist to reverse and rebill the claim in question; (iii) provide to the pharmacy or pharmacist the national drug code on which the increase or change is based; and (iv) make the increase or change effective for each similarly situated pharmacy or pharmacist who is subject to the applicable maximum allowable cost pricing information.

(5) If the appeal is denied, Navitus will provide to Participating Pharmacy or pharmacist the national drug code and the name of the national or regional pharmaceutical wholesalers operating in this state which have the drug currently in stock at a price below the maximum allowable cost pricing information.

(6) Every 90 days, Navitus will report to the Florida Office of Insurance Regulation the total number of appeals received and denied in the preceding 90-day period, with an explanation or reason for each denial, for each specific drug for which an appeal was submitted pursuant to this paragraph.

6. This Addendum constitutes the entire and complete understanding between the parties regarding the subject matter hereof and supersedes all previous discussions, representations, proposals, offers, counteroffers, and writings between the parties that may have occurred before entering into this Addendum.

7. In the event that any statute referenced herein is amended, superseded, or otherwise modified by legislative or regulatory action of the State of Florida, such modified or successor statute shall govern and control to the fullest extent permitted by law.

KENTUCKY STATE ADDENDUM
TO THE NAVITUS PARTICIPATING PHARMACY AGREEMENT

This Kentucky Addendum ("Addendum") applies to the extent that Participating Pharmacy dispenses outpatient prescriptions and drug products and provides pharmaceutical services to Members. All definitions used in this Addendum, which are not otherwise defined, have the meanings assigned to them in the Participating Pharmacy Agreement ("Agreement"), which Navitus and Participating Pharmacy previously executed. Both parties desire for the Agreement and the services provided thereunder to comply with all applicable Laws and regulations. This Addendum is intended to clarify the parties' responsibilities under the Laws of the State of Kentucky.

Now therefore, Navitus and Participating Pharmacy agree as follows:

1. Effectiveness of Addendum. If any provision of this Addendum conflicts with the terms or definitions of the Agreement, the terms of this Addendum will control with respect to Payors subject to Kentucky Law or regulation. To the extent that Participating Pharmacy provides Covered Pharmacy Services to Members of Payors licensed under Kentucky Law, Participating Pharmacy agrees to comply with any requirements for participation as a Participating Pharmacy in Kentucky as required by applicable Law. The terms of this Addendum will apply solely with regard to Covered Pharmacy Services provided to Members of Payors licensed as a health carrier under Kentucky Law and will not be deemed to amend the terms of the Agreement for Payors licensed in other states as a health carrier or for Covered Pharmacy Services not otherwise under the jurisdiction of the State of Kentucky, which may be covered by the requirements of other states. In the event of a conflict between the terms set forth in this Addendum and the terms set forth in the Agreement this Addendum shall control for Covered Pharmacy Services.

2. Pursuant to Kentucky Revised Statutes Annotated ("KRS") § 304.17A-595, to the extent permitted under federal law, Navitus shall be prohibited from:

(a) reducing payment for Covered Pharmacy Services, directly or indirectly, under a reconciliation process to an effective rate of reimbursement. This prohibition shall include, without limitation, creating, imposing, or establishing direct or indirect remuneration fees, generic effective rates, dispensing effective rates, brand effective rates, any other effective rates, in-network fees, performance fees, point-of-sale fees, retroactive fees, pre-adjudication fees, post-adjudication fees, and any other mechanism that reduces, or aggregately reduces, payment for Covered Pharmacy Services;

(b) retroactively denying, reducing reimbursement for, or seeking any refunds or recoupments for a claim for Covered Pharmacy Services, in whole or in part, from the Participating Pharmacy after returning a paid claim response as part of the adjudication of the claim, including claims for the cost of a medication or dispensed product and claims for Covered Pharmacy Services that are deemed ineligible for coverage, unless one (1) or more of the following occurred:
   (i) The original claim was submitted fraudulently; or
   (ii) The Participating Pharmacy received an actual overpayment;

(c) Reimbursing the Participating Pharmacy for a prescription drug or other service at a net amount that is lower than the amount the insurer, pharmacy benefit manager, or other administrator reimburses itself or a pharmacy affiliate for the same:

 Initials: _____

(i) Prescription drug by national drug code number; or
(ii) Service;

(d) Collecting cost sharing from a Participating Pharmacy that was provided to the Participating Pharmacy by an insured for the provision of Covered Pharmacy Services under the health plan; and

(e) Designating a prescription drug as a specialty drug unless the drug is a limited distribution drug that:
(i) Requires special handling; and
(ii) Is not commonly carried at retail pharmacies or oncology clinics or practices; and

3. Notwithstanding any other law, provide the following minimum reimbursements to the Participating Pharmacy for each prescription drug or other service provided by the Participating Pharmacy:

(a) Except as provided in subdivision b. of this subparagraph, reimbursement for the cost of the drug or other service at an amount that is not less than:
(i) The national average drug acquisition cost for the drug or service at the time the drug or service is administered, dispensed, or provided; or
(ii) If the national average drug acquisition cost is not available at the time a drug is administered or dispensed, the wholesale acquisition cost for the drug at the time the drug is administered or dispensed.

(b) The minimum reimbursement for the cost of a drug or other service required under this subparagraph shall not apply to a pharmacy permitted under KRS Chapter 315 with a designated pharmacy type of “retail chain” on file with the Kentucky Board of Pharmacy, or a pharmacist practicing at such a pharmacy, until a determination by the commissioner under subparagraph 2.a. of this paragraph has taken effect.

(c) For purposes of complying with this subparagraph, the insurer, pharmacy benefit manager, or other administrator shall utilize the most recently published monthly national average drug acquisition cost as a point of reference for the ingredient drug product component of a pharmacy's or pharmacist's reimbursement for drugs appearing on the national average drug acquisition cost list; and

(d) Except as provided in subdivision b. of this subparagraph, for health plan years beginning on or after January 1, 2027, reimbursement for a professional dispensing fee that is not less than the average cost to dispense a prescription drug in an ambulatory pharmacy located in Kentucky, as determined by the commissioner in an administrative regulation promulgated in accordance with KRS Chapter 13A.

(i) The minimum dispensing fee required under subdivision a. of this subparagraph shall not apply to a mail-order pharmaceutical distributor, including a mail-order pharmacy.

(ii) For health plan years beginning prior to January 1, 2027, and for any future health plan years for which a determination by the commissioner under subdivision a. of this subparagraph has not taken effect, the minimum dispensing fee for a pharmacy permitted under KRS Chapter 315 with a designated pharmacy type of “retail

independent" on file with the Kentucky Board of Pharmacy, or a pharmacist practicing at such a pharmacy, shall be not less than ten dollars and sixty-four cents ($10.64).

4. To the extent permitted under federal law and except as provided in KRS § 304.17A-595, pursuant to KRS § 304.17A-597 to the extent Navitus provides Covered Pharmacy Services, Navitus shall not:

(a) Require or incentivize an insured to use a mail-order pharmaceutical distributor, including a mail-order pharmacy.

(b) Conduct prohibited under this subparagraph includes but is not limited to imposing any cost-sharing requirement, fee, drug supply limitation, or other condition relating to Covered Pharmacy Services received from a retail pharmacy that is greater, or more restrictive, than what would otherwise be imposed if the insured used a mail-order pharmaceutical distributor, including a mail-order pharmacy;

(c) Prohibit a Participating Pharmacy from, or impose a penalty on a Participating Pharmacy for, the following:
   (i) Selling a lower cost alternative to an insured, if one is available; or
   (ii) Providing information to an insured under subsection (2) of this section;

(d) Discriminate against any pharmacy or pharmacist that is:
   (i) Located within the geographic coverage area of the health plan; and
   (ii) Willing to agree to, or accept, reasonable terms and conditions established for participation in the insurer's, pharmacy benefit manager's, other administrator's, or health plan's network;

(e) Impose limits, including quantity limits or refill frequency limits, on an insured's access to medication from a pharmacy that are more restrictive than those existing for a pharmacy affiliate;

(f) Require or incentivize an insured to receive Covered Pharmacy Services from a pharmacy affiliate.

(g) Conduct prohibited under this subparagraph includes but is not limited to:
   (i) Requiring or incentivizing an insured to obtain a specialty drug from a pharmacy affiliate;
   (ii) Charging less cost sharing to insureds that use pharmacy affiliates than what is charged to insureds that use nonaffiliated pharmacies; and
   (iii) Providing any incentives for insureds that use pharmacy affiliates that are not provided for insureds that use nonaffiliated pharmacies
   (iv) The requirements under this subparagraph (g) shall not be construed to prohibit:
      (1) Communications to insureds regarding networks and prices if the communication is accurate and includes information about all eligible nonaffiliated pharmacies; or

      (2) Requiring an insured to utilize a network that may include pharmacy affiliates in order to receive coverage under the plan, or providing financial incentives for utilizing that network, if the insurer, pharmacy benefit manager, or other administrator complies with this section and Section 2 of this Act; or

(h) Interfere with an insured's right to choose the insured's network pharmacy of choice. b. For purposes of this subparagraph, interfering includes inducing, steering, offering financial or other incentives, and imposing a penalty, including but not limited to:
    (i) Promoting one (1) participating pharmacy over another;
    (ii) Offering a monetary advantage;
    (iii) Charging higher cost sharing; and
    (iv) Reducing an insured's allowable reimbursement for Covered Pharmacy Services.

5. Pursuant to KRS § 304.17A-597 and to the extent Navitus provides Covered Pharmacy Services, Navitus shall:

(a) Provide equal access and incentives to all pharmacies within the insurer's, pharmacy benefit manager's, other administrator's, or health plan's network; and

(b) Offer all pharmacies located in the health plan's geographic coverage area eligibility to participate in the insurer's, pharmacy benefit manager's, other administrator's, or health plan's network under identical reimbursement terms for the provision of Covered Pharmacy Services; and

6. A pharmacist shall have the right to provide a Member information regarding lower cost alternatives to assist in making informed decisions.

7. Participating Pharmacy may not, under any circumstance, including nonpayment of moneys due Participating Pharmacy by Plan Sponsor and/or Navitus, insolvency of Plan Sponsor, Navitus, or breach of the Agreement, bill charge, collect a deposit, seek compensation, remuneration, or reimbursement from, or have any recourse against Members, or any persons acting on their behalf, for services provided in accordance with the Agreement. This provision shall not prohibit collection of deductible amounts, copayment amounts, coinsurance amounts, and amounts for services that are not covered. This provision shall survive the termination of the Agreement. (See KRS §§ 304.17A-254(2); 304.17A-527(1)(a), (c); 304.17A-310(5); 304.17C-060(1)(a), (b); 806 KAR 17:300 (Section 3); 806 KAR 17:440 (Section 3))

8. In the event the Agreement is terminated for any reason, other than a quality-of-care issue or fraud, Participating Pharmacy shall continue to provide services and Navitus shall continue to reimburse Participating Pharmacy in accordance with the Agreement until the Member is discharged from an inpatient facility, or the active course of treatment is completed, whichever is greater. In the case of a pregnant woman, Participating Pharmacy shall continue to provide services through the end of the post-partum period if the pregnant woman is in her fourth or later month of pregnancy at the time the Agreement terminates. This provision shall survive termination of the agreement. (See KRS § 304.17A-527(1)(b)-(c); 806 KAR 17:300 (Section 3))

9. In the event of the insolvency of Plan Sponsor or Navitus, Participating Pharmacy shall continue providing Covered Drugs to Members for the duration of the contract period for which premiums have been paid or until the date of discharge from an inpatient facility, whichever is longer. (See KRS § 304.17A-310(6))

10. Upon written request, Navitus shall provide or make available to Participating Pharmacy, when contracting or renewing an existing contract with Participating Pharmacy, the payment or fee schedules or other information sufficient to enable Participating Pharmacy to determine the manner and amount of payments for Participating Pharmacy's services under the Agreement prior to the final execution or renewal

 Initials: _____

of the contract and shall provide Participating Pharmacy any change in such payment or fee schedules at least 90 days prior to the effective date of the change. (See KRS §§ 304.17A-254(7); 304.17A-527(1)(d); 304.17A-577; 806 KAR 17:300 (Section 3))

11. If Participating Pharmacy enters into any subcontract agreement with another provider to provide Covered Drugs to Members where the subcontracted provider will bill Navitus or Members directly for the subcontracted services, the subcontract agreement must meet all requirements of Title XXV, Chapter 304, Subtitle 17A of the Kentucky Insurance Code and be filed with the Kentucky Commissioner of Insurance. (See KRS §§ 304.17A-527(1)(e); 304.17C-060(1)(c); 806 KAR 17:300 (Section 3); 806 KAR 17:440 (Section 3))

12. The reimbursement rate identified in the Participating Pharmacy Agreement shall apply to all Covered Pharmacy Services rendered by Participating Pharmacy to all Plan Sponsors' Members. (See KRS § 304.17A-728; 806 KAR 17:300 (Section 3))

13. Navitus and Participating Pharmacy shall comply with See KRS §§ 304.17A-700 to 304.17A-730, 205.593, 304.14-135, and 304.99-123 regarding payment of claims. (See KRS § 304.17A-726)

14. To the extent the Agreement requires Participating Pharmacy to submit claims electronically, payment shall be made electronically, if requested by Participating Pharmacy, for clean claims submitted electronically in the form required by Navitus and/or Plan Sponsor if Participating Pharmacy agrees to accept claims details for these payments electronically and provides accurate electronic funds transfer information to Navitus and the claims comply with 45 CFR Part 142. (See KRS § 304.17A-705)

15. Any audit of Participating Pharmacy's records under this Agreement, except for audits conducted on behalf of a state agency pursuant to KRS Chapter 205 or audits resulting from allegations of fraud, willful misrepresentation, or abuse, shall comply with Chapter 304, Subtitle 17A of KRS §§ 304.17A-741 and 304.17A-743. (See KRS §§ 304.17A-740; 304.17A-745; 304.17A-747)

16. The sources used by Navitus to calculate the drug product reimbursement paid for covered drugs available under pharmacy health benefit plans administered by Navitus are identified in the Agreement, including the pharmacy manual. (See KRS. § 304.17A-162(1)(a))

17. The following shall apply with respect to Navitus MAC Lists:

(a) The national drug pricing compendia and/or sources used to obtain drug price data utilized by Navitus in establishing maximum allowable cost pricing are identified on the Navitus MAC Lists

(b) Participating Pharmacy locations in Kentucky subject to Navitus MAC Lists may appeal a maximum allowable cost for a specific drug or drugs on Navitus MAC Lists as follows:
    (i) Participating Pharmacy must initiate the appeal within 60 days following the initial claim through the MRx web address, detailing the challenge to the Navitus maximum allowable cost, and submitting supporting information and/or documentation.

    (ii) Navitus will investigate and resolve the appeal within 10 days.

(c) If the appeal is denied, Navitus will provide the reason for the denial and identify the NDC of a drug product that may be purchased by pharmacies at a price at or below the maximum allowable cost.

(d) If the appeal is upheld, Navitus will make the change in the maximum allowable cost and Participating Pharmacy can then reverse and rebill the claim in question. (See KRS § 304.017A-162)

(e) This Section 17 applies only with respect to MAC Lists owned and/or controlled by Navitus.

18. This Addendum constitutes the entire and complete understanding between the parties regarding the subject matter hereof and supersedes all previous discussions, representations, proposals, offers, counteroffers, and writings between the parties that may have occurred before entering into this Addendum.

19. In the event that any statute referenced herein is amended, superseded, or otherwise modified by legislative or regulatory action of the State of Kentucky, such modified or successor statute shall govern and control to the fullest extent permitted by law.

MAINE STATE ADDENDUM
TO THE NAVITUS PARTICIPATING PHARMACY AGREEMENT

Navitus and Participating Pharmacy have mutually executed a Participating Pharmacy Agreement (the "Agreement") pursuant to which Participating Pharmacy agreed to dispense outpatient prescriptions and drug products and to provide pharmaceutical services to Members. All definitions used in this Addendum, which are not otherwise defined, have the meanings assigned to them in the Agreement. Both parties desire for the Agreement and the services provided thereunder to comply with all applicable Laws and regulations. This Addendum is intended to clarify the parties' responsibilities under the Laws of the State of Maine.

Now therefore, Navitus and Participating Pharmacy agree as follows:

1. Effectiveness of Addendum. If any provision of this Addendum conflicts with the terms or definitions of the Agreement, the terms of this Addendum will control with respect to Payors subject to Maine Law or regulation. To the extent that Participating Pharmacy provides Covered Pharmacy Services to Members of Payors licensed under Maine Law, Participating Pharmacy agrees to comply with any requirements for participation as a Participating Pharmacy in Maine as required by applicable Law. The terms of this Addendum will apply solely with regard to Covered Pharmacy Services provided to Members of Payors licensed as a health carrier under Maine Law and will not be deemed to amend the terms of the Agreement for Payors licensed in other states as a health carrier or for Covered Pharmacy Services not otherwise under the jurisdiction of the State of Maine, which may be covered by the requirements of other states. In the event of a conflict between the terms set forth in this Addendum and the terms set forth in the Agreement, this Addendum shall control for Covered Pharmacy Services.

2. Definitions. The following state-specific definition shall apply for purposes of this Addendum only (The NCPDP state code for the State of Maine is ""):

a. "Clean Claim" means a claim that has no defect or impropriety, including any lack of any required substantiating documentation, or particular circumstance requiring special treatment that prevents timely payment from being made on the claim.

3. The following state-specific provisions shall apply for purposes of this Addendum only:

a. Plan Requirements. Pursuant to the Maine Revised Statutes 24-A § 4303, Navitus and the Participating Pharmacy mutually agree to waive the requirement of 60-days' notice for amendments to provider agreements, including this Agreement, manuals, policies, and procedure documents. Participating Pharmacy shall receive notice of changes to the Agreement as described in section 11.05 of the Agreement.

b. Termination. Pursuant to Maine Revised Statutes 24-A § 4303, section 12.02(a) of the Agreement between Navitus and the Participating Pharmacy is amended to permit either party to terminate the agreement within 60 days' after notice of a material breach. In accordance with Maine Revised Statutes 24-A § 4303, section 12.02(b) of the Agreement between Navitus and the Participating Pharmacy is amended to permit immediate termination of the Agreement only upon the following occurrences:

 Initials: _____

a. Imminent harm to patient care;
b. A final determination of fraud by a governmental agency; or
c. A final disciplinary action by a state licensing board or other governmental agency that impairs the ability of a provider to practice.

c. Payment of Claims. Pursuant to Maine Revised Statutes 24-A § 4317, payment with respect to all Clean Claims submitted by a Participating Pharmacy that is not a mail-order pharmacy or under contract to a long-term care facility shall be issued, mailed or otherwise transmitted within 21 calendar days for claims electronically submitted or within 30 calendar days for claims submitted by other means.

This Addendum constitutes the entire and complete understanding between the parties regarding the subject matter hereof and supersedes all previous discussions, representations, proposals, offers, counteroffers, and writings between the parties that may have occurred before entering into this Addendum.

In the event that any statute referenced herein is amended, superseded, or otherwise modified by legislative or regulatory action of the State of Maine, such modified or successor statute shall govern and control to the fullest extent permitted by law.

NEBRAKSA STATE ADDENDUM
TO THE NAVITUS PARTICIPATING PHARMACY AGREEMENT

Navitus and Participating Pharmacy have mutually executed a Participating Pharmacy Agreement (the "Agreement") pursuant to which Participating Pharmacy agreed to dispense outpatient prescriptions and drug products and to provide pharmaceutical services to Members. All definitions used in this Addendum, which are not otherwise defined, have the meanings assigned to them in the Agreement. Both parties desire for the Agreement and the services provided thereunder to comply with all applicable Laws and regulations. This Addendum is intended to clarify the parties' responsibilities under the Laws of the State of Nebraska.

Now therefore, Navitus and Participating Pharmacy agree as follows:

1. Effectiveness of Addendum. If any provision of this Addendum conflicts with the terms or definitions of the Agreement, the terms of this Addendum will control with respect to Payors subject to Nebraska Law or regulation. To the extent that Participating Pharmacy provides Covered Pharmacy Services to Members of Payors licensed under Nebraska Law, Participating Pharmacy agrees to comply with any requirements for participation as a Participating Pharmacy in Nebraska as required by applicable Law. The terms of this Addendum will apply solely with regard to Covered Pharmacy Services provided to Members of Payors licensed as a health carrier under Nebraska Law and will not be deemed to amend the terms of the Agreement for Payors licensed in other states as a health carrier or for Covered Pharmacy Services not otherwise under the jurisdiction of the State of Nebraska, which may be covered by the requirements of other states. In the event of a conflict between the terms set forth in this Addendum and the terms set forth in the Agreement, this Addendum shall control for Covered Pharmacy Services.

2. Participating Contract. Pursuant to § 44-4606 of the Nebraska Revised Statute, § 2.09 and § 4.01:

a The Agreement between Navitus and the Participating Pharmacy is amended to not limit or penalize pharmacies or pharmacists from sharing health care information deemed relevant. This includes details such as treatment options, risks, alternatives, availability of therapies, consultations, tests, decisions made by utilization reviewers, authorization processes for services, and information on financial incentives and structures used by health insurers.

b Navitus shall not prohibit a pharmacy or pharmacist from discussing information regarding the total cost for a pharmacist service for a prescription drug or from selling a more affordable alternative to the covered person if a more affordable alternative is available.

c Navitus shall not or restrict limit disclosure of information to the director, law enforcement or a state or federal government official provided that the recipient of the information represents that such recipient has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and Prior to disclosure of information designated as confidential, the pharmacist or pharmacy marks as confidential any document in which the information appears; or Requests confidential treatment for any oral communication of the information.

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3. MAC Pricing. Pursuant to § 44-4608 of the Nebraska Revised Statute, the Agreement between Navitus and Participating Pharmacy now includes a process to appeal, investigate and resolve disputes regarding maximum allowable cost price. The process shall include:

a. fifteen-business-day (15) limit on the right to appeal following submission of an initial claim by a pharmacy;
b. A requirement that any appeal be investigated and resolved within seven (7) business days after the appeal is received by Navitus; and
c. A requirement that Navitus provide a reason for any denial of an appeal and identify the national drug code for the drug that may be purchased by the pharmacy at a price at or below the price on the maximum allowable cost price list as determined by the pharmacy benefit manager.
d. If an appeal is determined to be valid by Navitus, then Navitus shall:
    i. Make an adjustment in the drug price no later than one day after the appeal is resolved; and
    ii. Permit the appealing pharmacy to reverse and rebill the claim in question, using the date of the original claim.

4. 340B. The following is applicable to 340B entities:

a 340B entities will be reimbursed at the same rates as non-340B entities. Reimbursement rates for 340B entities shall not be lower than the rates for non-340B entities.

b 340B entities will not be charged any fees, chargebacks, or adjustments unless those same fees, chargebacks, or adjustments are also applied equally to non-340B entities.

c 340B entities will not be excluded from their provider network based on criteria that are not also applied equally to non-340B entities.

d 340B entities will not be required to include any special modifiers on claims to identify 340B drugs. Claim requirements shall be the same for 340B and non-340B entities.

5. Pharmacy Communications Rights and Protections (GAG Clause). Pursuant to § 44-4606 of the Nebraska Revised Statute the following is added to the Agreement:

a The Pharmacy/Pharmacist may freely communicate and without penalty with covered persons regarding:
    i Treatment options, risks, and alternatives
    ii Available therapies, consultations, or tests
    iii Coverage decisions and their reasoning
    iv Service authorization processes
    v Financial incentives or structures used by the health carrier

b The Pharmacy/Pharmacist may discuss total prescription drug costs with patients, offer more affordable alternatives when available. Nothing in the Agreement will be construed to prohibit either discussions from taking place.

c The Pharmacy/Pharmacist may disclose information to authorized officials, provided:

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i The receiving official has legal authority to maintain confidentiality
ii Confidential documents are clearly marked as such
iii Confidential oral communications are identified before disclosure

d Pharmacy Benefit Manager shall not terminate contracts or penalize pharmacies for disclosing PBM practices (except verified trade secrets or breaching agreed upon non-disclosure provisions) or from sharing contract portions with officials for compliance verification.

e Covered persons shall pay the lesser of their plan's cost-sharing amount, or the actual cost of the covered prescription drug. In no case shall patients be required to pay more than these amounts.

Unless otherwise prohibited by Law, the parties agree that an electronic copy of a signed contract, or an electronically signed contract, has the same force and legal effect as a contract executed with an original ink signature. The term “electronic copy of a signed contract” refers to a transmission by facsimile, electronic mail, or other electronic means of a copy of an original signed contract in a portable document format.

This Addendum constitutes the entire and complete understanding between the parties regarding the subject matter hereof and supersedes all previous discussions, representations, proposals, offers, counteroffers, and writings between the parties that may have occurred before entering into this Addendum.

In the event that any statute referenced herein is amended, superseded, or otherwise modified by legislative or regulatory action by the State of Nebraska, such modified or successor statute shall govern and control to the fullest extent permitted by law.

SOUTH CAROLINA STATE ADDENDUM
TO THE NAVITUS PARTICIPATING PHARMACY AGREEMENT

This South Carolina Addendum ("Addendum") applies to the extent that Participating Pharmacy dispenses outpatient prescriptions and drug products and provides pharmaceutical services to Members. All definitions used in this Addendum, which are not otherwise defined, have the meanings assigned to them in the Participating Pharmacy Agreement ("Agreement"), which Navitus and Participating Pharmacy previously executed. Both parties desire for the Agreement and the services provided thereunder to comply with all applicable Laws and regulations. This Addendum is intended to clarify the parties' responsibilities under the Laws of the State of South Carolina.

Now therefore, Navitus and Participating Pharmacy agree as follows:

1. Effectiveness of Addendum. If any provision of this Addendum conflicts with the terms or definitions of the Agreement, the terms of this Addendum will control with respect to Payors subject to South Carolina Law or regulation. To the extent that Participating Pharmacy provides Covered Pharmacy Services to Members of Payors licensed under South Carolina Law, Participating Pharmacy agrees to comply with any requirements for participation as a Participating Pharmacy in South Carolina as required by applicable Law. The terms of this Addendum will apply solely with regard to Covered Pharmacy Services provided to Members of Payors licensed as a health carrier under South Carolina Law and will not be deemed to amend the terms of the Agreement for Payors licensed in other states as a health carrier or for Covered Pharmacy Services not otherwise under the jurisdiction of the State of South Carolina, which may be covered by the requirements of other states. In the event of a conflict between the terms set forth in this Addendum and the terms set forth in the Agreement this Addendum shall control for Covered Pharmacy Services.

2. Definitions.

    a. "Audit" as used in this addendum is defined pursuant to § 38-71-1810 of the South Carolina Code of State Regulations Annotated as an evaluation, investigation, or review of claims paid to a pharmacy that takes place at the pharmacy location and does not include review of claims or claims payments that an insurer conducts as a normal course of business. Nothing in this definition limits the review of claims or claims payments through an electronic or algorithmic system designed to reduce fraud, waste, or abuse, provided that recoupments may not be calculated based on extrapolation pursuant to Section 38-71-1810(21).

3. Pharmacy Right to External Appeals. Pursuant to Section 69-77 of the South Carolina Code of State Regulations Annotated, Participating Pharmacy has the right to an external appeal once a pharmacy as exhausted Navitus internal appeal process.

    a. Participating Pharmacy has the right to an external review of denials by Navitus of internal appeals of provider reimbursement and appeals of recoupments arising out of pharmacy audits.

 Initials: _____

b. The Director or his designee may delegate the review and resolution of a pharmacy's appeal under this paragraph to an independent review organization (IRO), and any decision by the IRO shall have the same force and effect as a decision by the Director.

c. A contracted pharmacy that receives a provider's reimbursement for a drug subject to maximum allowable cost pricing that is less than the net amount that the network provider paid to the suppliers of the drug shall have the right, after denial of an internal appeal, to appeal the decision of the PBM to the Director for an external review.

d. Any pharmacy that believes recoupment amounts arising out of a PBM's final audit report were calculated in violation of the Code shall have the right to appeal the recoupment to the Director or his designee for an external review.

4. Requests for External Review.

a. An appeal must:

i. Be submitted electronically on a form made available by the Department on its website within 60 calendar days of the pharmacy's receipt of the PBM's final determination resolving the pharmacy's initial appeal or within 30 calendar days of the pharmacy's receipt of the PBM's final audit report; unless a different timeframe is approved in writing pursuant to subsection (2) of this regulation.

ii. Contain a summary of:
- The grounds of the appeal to the Director;
- The relief requested by the pharmacy; and
- The basis on which the pharmacy believes it is due the relief.

iii. Include a copy of the written decision rendered by the PBM;

iv. Contain a copy of the invoice(s) showing the pharmacy's purchase price for the drug or medical product or device at issue, if applicable;

v. Contain a list of all discounts, price concessions, rebates or other reductions, excluding cash discounts, that were, or should have been, reported to the PBM including supporting documentation for each discount, price concession, rebate or other reduction, if applicable;

vi. Contain a certification by the applicant that all information submitted is true and accurate to the best of the applicant's knowledge; and

vii. Provide any other documentation or information requested by the director or his designee regarding the pharmacy's appeal.

b. A pharmacy is not entitled to an external review of an appeal denial until the pharmacy has exhausted the PBM's internal appeal process.

c. Within 7 business days from the date a request for an external review is filed or the date all information requested by the Director or his designee has been received, the Director or his designee shall:

   i. Assign an independent review organization from the list of approved independent review organizations compiled and maintained pursuant to Section E of this regulation to conduct an external review, and send the documents and any information considered in making the adverse determination to the independent review organization; or

   ii. Inform the pharmacy in writing that the request does not meet the criteria for external review pursuant to this regulation and include the reason for nonacceptance.

d. Within 7 business days after the independent review organization's receipt from the Director or his designee of the request for external review, the independent review organization shall determine whether all the information, certifications, and forms required to process the external review have been provided. The independent review organization shall immediately notify the pharmacy provider and/or Pharmacy Benefits Manager in writing if additional information is required.

e. If the request for an external review is not:
   i. complete, the independent review organization shall inform the pharmacy provider what information or materials are needed to make the request complete; or

   ii. accepted for external review, the independent review organization shall inform the pharmacy and the PBM in writing of the reasons for its nonacceptance.

f. If a request for external review is accepted for external review, the independent review organization shall notify the PBM and the pharmacy.

g. Upon receipt of the request for external review, the independent review organization shall render a decision within 30 days unless a written extension is granted by the Director or his designee.

5. External Review Findings

a. If the independent review organization determines the pharmacy benefits manager reimbursed a pharmacy or pharmacist in an amount inconsistent with the provisions of this Regulation and Section 38-71-2230 *et seq.,* of the Code of Laws of South Carolina, the pharmacy benefit manager must
   i. Promptly make the change in the reimbursement rate effective as of the date the external review is resolved;
   ii. Permit the appealing pharmacy or pharmacist to reverse and rebill the claim in question;
   iii. Reimburse the pharmacy the amount of the filing fee; and
   iv. Promptly make the change effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List effective as of the date the external review is resolved.

Initials: _____

b. If the independent review organization determines the recoupments of any funds disputed on the basis of an audit were calculated in violation of 38-71-1810 et seq, then the pharmacy benefit manager must promptly refund any amounts due to the responsible party as contractually agreed upon by the parties in the audit and the PBM must reimburse the pharmacy the amount of the filing fee.

c. An external review decision is binding on the pharmacy benefit manager and the appealing pharmacy or pharmacist. An appealing pharmacy or pharmacist may not file a subsequent request for an external review involving the same type of prescription drug unless there is an update to the reimbursement metric that would change the circumstances of the pharmacy's or pharmacist's reimbursement.

d. The pharmacy benefits manager must pay for all costs related to the external review except for the initial filing fee if not reimbursable by the PBM under subsections (C)(1) or (2) of this regulation.

e. The filing fee associated with a pharmacist's request for an external review is to be retained by the department for administration of Chapter 71. This filing fee shall be set by the department and published on its website.

f. If the Director determines the pharmacy or pharmacist has abused the external review process, he may require the pharmacy or pharmacist to pay for costs related to the external review.

6. The external review procedure shall be available to Participating Pharmacy following a denied internal appeal and a denied recoupment. Participating Pharmacy has the right to contact the South Carolina Department of Insurance director or his designee for assistance at 803-734-0398 or at PBMExtReview@doi.sc.gov or at the mailing address of PO Box 100105, Columbia, SC 29202-3105.

6. Pharmacy Audits. Pursuant to § 38-71-1810 of the South Carolina Code of State Regulations Annotated, Participating Pharmacy has a right to the following:

a. not have an audit initiated or scheduled during the first five days of any month without the express consent of the pharmacy, which shall cooperate with the auditor to establish an alternate date if the audit would fall within the excluded days, and no audit may be performed during a state of emergency declared by the Governor that applies to the pharmacy location unless the state of emergency extends beyond ninety days or is agreed to by the pharmacy location;
b. have an audit that involves clinical judgment be conducted with a pharmacist who is licensed and employed by or working under contract with the auditing entity;
c. not have clerical or recordkeeping errors, including typographical errors, scrivener's errors, and computer errors, on a required document or record considered fraudulent in the absence of any other evidence or serve as the sole basis of rejection of a claim; however, the provisions of this item do not prohibit recoupment of fraudulent payments;

d. have the auditing entity to provide the pharmacy, upon request, all records related to the audit in an electronic format or contained in digital media;
e. have at least thirty days to respond to an audit notice and to submit records requested by the auditing entity related to the audit in electronic format or by certified mail. If a pharmacy requests an extension during this thirty-day period, it must be granted an additional thirty days to respond. The auditing entity must confirm receipt of all materials and documentation provided by the pharmacy to the auditing entity;
f. have the properly documented records of a hospital or of a person authorized to prescribe controlled substances for the purpose of providing medical or pharmaceutical care for their patients transmitted by any means of communication approved by the auditing entity in order to validate a pharmacy record with respect to a prescription or refill for a controlled substance or narcotic drug pursuant to federal and state regulations;
g. have a projection of an overpayment or underpayment based on either the number of patients served with a similar diagnosis or the number of similar prescription orders or refills for similar drugs; however, the provisions of this item do not prohibit recoupments of actual overpayments unless the projection for overpayment or underpayment is part of a settlement by the pharmacy;
h. prior to the initiation of an audit, if the audit is conducted for an identified problem, have the audit limited to claims that are identified by prescription number or by range of prescription numbers;
i. if an audit is conducted for a reason other than described in item (h), have the audit limited to one hundred selected prescriptions per pharmacy benefits manager;
j. if an audit reveals the necessity for a review of additional claims, the audit may be conducted on-site;
k. except for audits initiated for the reason described in items (h) or (j), be subject to no more than one audit in one calendar year, unless fraud or misrepresentation is reasonably suspected;
l. be free of recoupments based on either of the following subitems unless defined within the billing, submission, or audit requirements set forth in the pharmacy provider manual not inconsistent with current State Board of Pharmacy Regulations, except for cases of Food and Drug Administration regulation or drug manufacturer safety programs in accordance with federal or state regulations:
    i. documentation requirements in addition to, or exceeding requirements for, creating or maintaining documentation prescribed by the State Board of Pharmacy;
    ii. a requirement that a pharmacy or pharmacist perform a professional duty in addition to, or exceeding, professional duties prescribed by the State Board of Pharmacy unless otherwise agreed to by contract with the auditing entity;
m. be subject, so long as a claim is made within the contractual claim submission time period, to recoupment only following the correction of a claim and to have recoupment limited to amounts paid in excess of amounts payable under the corrected claim unless a prescription error occurs. For purposes of this subsection, a prescription error includes, but is not limited to, wrong drug, wrong strength, wrong dose, or wrong patient;
n. be subject to reversals of approval, except for Medicare claims, for drug, prescriber, or patient eligibility upon adjudication of a claim only in cases in which the pharmacy obtained the adjudication by fraud or misrepresentation of claim elements;
o. be audited under the same standards and parameters as other similarly situated pharmacies audited by the same entity;

p. have at least thirty days following receipt of the preliminary audit report to produce documentation to address any discrepancy found during an audit;
q. have the option of providing documentation in electronic format or by certified mail;
r. have the period covered by an audit limited to twenty-four months from the date a claim was submitted to, or adjudicated by, a managed care organization, an insurer, a third-party payor, or an entity that represents responsible parties, unless a longer period is permitted by or under federal law;
s. have the preliminary audit report delivered to the pharmacy within one hundred twenty days after conclusion of the audit;
t. have a final audit report delivered to the pharmacy within ninety days after the end of the appeals period;
u. not have the accounting practice of extrapolation used in calculating recoupments or penalties for audits, unless otherwise required by federal requirements or federal plans; and
v. have the right to an external review pursuant to § 38-71-2240 of the South Carolina Code of State Regulations Annotated for any denied appeals of recoupment if the pharmacy believes the recoupment amounts were calculated in violation of these provisions.

7. This Addendum constitutes the entire and complete understanding between the parties regarding the subject matter hereof and supersedes all previous discussions, representations, proposals, offers, counteroffers, and writings between the parties that may have occurred before entering into this Addendum.

8. In the event that any statute referenced herein is amended, superseded, or otherwise modified by legislative or regulatory action of the State of South Carolina, such modified or successor statute shall govern and control to the fullest extent permitted by law.

TENNESSEE STATE ADDENDUM
TO THE NAVITUS PARTICIPATING PHARMACY AGREEMENT

Navitus and Participating Pharmacy have mutually executed a Participating Pharmacy Agreement (the "Agreement") pursuant to which Participating Pharmacy agreed to dispense outpatient prescriptions and drug products and to provide pharmaceutical services to Members. All definitions used in this Addendum, which are not otherwise defined, have the meanings assigned to them in the Agreement. Both parties desire for the Agreement and the services provided thereunder to comply with all applicable Laws and regulations. This Addendum is intended to clarify the parties' responsibilities under the Laws of the State of Tennessee.

Now therefore, Navitus and Participating Pharmacy agree as follows:

1. Effectiveness of Addendum. If any provision of this Addendum conflicts with the terms or definitions of the Agreement, the terms of this Addendum will control with respect to Payors subject to Tennessee Law or regulation. To the extent that Participating Pharmacy provides Covered Pharmacy Services to Members of Payors licensed under Tennessee Law, Participating Pharmacy agrees to comply with any requirements for participation as a Participating Pharmacy in Tennessee as required by applicable Law. The terms of this Addendum will apply solely with regard to Covered Pharmacy Services provided to Members of Payors licensed as a health carrier under Tennessee Law and will not be deemed to amend the terms of the Agreement for Payors licensed in other states as a health carrier or for Covered Pharmacy Services not otherwise under the jurisdiction of the State of Tennessee, which may be covered by the requirements of other states. In the event of a conflict between the terms set forth in this Addendum and the terms set forth in the Agreement, this Addendum shall control for Covered Pharmacy Services.

2. Prohibited Terms or Conditions in the Contract. In accordance with § 56-7-3116 of Tennessee Code Annotated, no language in the Navitus Participating Pharmacy Agreement or this Addendum shall be construed to require a pharmacy or pharmacist to dispense a drug or other product to a patient contrary to a pharmacist's professional judgment.

3. Mutual Agreement. In accordance with § 56-7-3118 of Tennessee Code Annotated, Navitus and Participating Pharmacy have mutually executed a Participating Pharmacy Agreement outlining the terms and conditions for the provision of pharmacy services.

4. Utilization of any pharmacy in state. In accordance with § 56-7-3121 of Tennessee Code Annotated, no language in the Navitus Credentialing Application, Participating Pharmacy Agreement, or this Addendum shall be construed as prohibiting a pharmacy from participation in a Navitus network within Tennessee if the Tennessee and federally licensed pharmacy is willing to accept the terms and conditions established for a network.

5. Disclosure of Reimbursement. In accordance with § 56-7-3203 of Tennessee Code Annotated, Navitus shall not in any way restrict any pharmacy from disclosing to the member or their representative the actual reimbursement for a particular prescription or covered service. Participating Pharmacy may disclose the actual reimbursement either orally or in writing on any document to the member.

6. Low Volume Certification. In accordance with Tenn. Comp. R. & Regs. 0780-01-95-.10(1)(b) and § 56-7-3206 of Tennessee Code Annotated, Participating Pharmacy agrees to provide annual low-volume certification to Navitus for receipt of the enhanced dispensing fee for the following calendar year. The

certification must contain a statement that the information submitted is true and accurate to the best of the knowledge of the individual filing and include proof of Participating Pharmacy's actual prescription volume. Certifications that do not include both of the above requirements are not considered complete, and Navitus is not obligated to pay the enhanced dispensing fee until receipt of the completed certification. Navitus agrees to comply with the additional provisions for certification in accordance with Tenn. Comp. R. & Regs. 0780-01-95-.10(3) and (4).

7. 340B. The following is applicable to 340B entities:

    a 340B entities will be reimbursed at the same rates as non-340B entities. Reimbursement rates for 340B entities shall not be lower than the rates for non-340B entities.

    b 340B entities will not be charged any fees, chargebacks, or adjustments unless those same fees, chargebacks, or adjustments are also applied equally to non-340B entities.

    c 340B entities will not be excluded from their provider network based on criteria that are not also applied equally to non-340B entities.

    d 340B entities will not be required to include any special modifiers on claims to identify 340B drugs. Claim requirements shall be the same for 340B and non-340B entities.

Unless otherwise prohibited by Law, the parties agree that an electronic copy of a signed contract, or an electronically signed contract, has the same force and legal effect as a contract executed with an original ink signature. The term "electronic copy of a signed contract" refers to a transmission by facsimile, electronic mail, or other electronic means of a copy of an original signed contract in a portable document format.

This Addendum constitutes the entire and complete understanding between the parties regarding the subject matter hereof and supersedes all previous discussions, representations, proposals, offers, counteroffers, and writings between the parties that may have occurred before entering into this Addendum.

In the event that any statute referenced herein is amended, superseded, or otherwise modified by legislative or regulatory action by the State of Tennessee, such modified or successor statute shall govern and control to the fullest extent permitted by law.

VERMONT STATE ADDENDUM
TO THE NAVITUS PARTICIPATING PHARMACY AGREEMENT

Navitus and Participating Pharmacy have mutually executed a Participating Pharmacy Agreement (the "Agreement") pursuant to which Participating Pharmacy agreed to dispense outpatient prescriptions and drug products and to provide pharmaceutical services to Members. All definitions used in this Addendum, which are not otherwise defined, have the meanings assigned to them in the Agreement. Both parties desire for the Agreement and the services provided thereunder to comply with all applicable Laws and regulations. This Addendum is intended to clarify the parties' responsibilities under the Laws of the State of Vermont.

Now therefore, Navitus and Participating Pharmacy agree as follows:

1. Effectiveness of Addendum. If any provision of this Addendum conflicts with the terms or definitions of the Agreement, the terms of this Addendum will control with respect to Payors subject to Vermont Law or regulation. To the extent that Participating Pharmacy provides Covered Pharmacy Services to Members of Payors licensed under Vermont Law, Participating Pharmacy agrees to comply with any requirements for participation as a Participating Pharmacy in Vermont as required by applicable Law. The terms of this Addendum will apply solely with regard to Covered Pharmacy Services provided to Members of Payors licensed as a health carrier under Vermont Law and will not be deemed to amend the terms of the Agreement for Payors licensed in other states as a health carrier or for Covered Pharmacy Services not otherwise under the jurisdiction of the State of Vermont, which may be covered by the requirements of other states. In the event of a conflict between the terms set forth in this Addendum and the terms set forth in the Agreement, this Addendum shall control for Covered Pharmacy Services.

2. Pharmacy Communication Rights and Protections. Pursuant to § 9473, section 2.09 and section 4.01 of the Vermont Statutes Annotated (V.S.A.), the Agreement between Navitus and the Participating Pharmacy is amended to not limit or penalize pharmacies or pharmacists from sharing health care information deemed relevant. This includes details such as treatment options, risks, alternatives, availability of therapies, consultations, tests, decisions made by utilization reviewers, authorization processes for services, and information on financial incentives and structures used by health insurers.

3. Mutual Agreement. Pursuant to § 56-7-3118 of the VSA, Navitus and Participating Pharmacy have mutually executed a Participating Pharmacy Agreement outlining the terms and conditions for the provision of pharmacy services.

4. Pharmacy Manual Updates. Navitus shall use polices or manuals to augment the content of the contract with a health care provider. Navitus shall ensure that those polices or manuals contain sufficient information to allow providers to understand and comply with the content. For any new policy or manual, Navitus shall provide notice of the new policy, manual or change to each participating provider in writing not fewer than sixty (60) days prior to effective date of the policy or change where applicable.

5. 340B. The following is applicable to 340B entities:

a 340B entities will be reimbursed at the same rates as non-340B entities. Reimbursement rates for 340B entities shall not be lower than the rates for non-340B entities.

 Initials: _____

b 340B entities will not be charged any fees, chargebacks, or adjustments unless those same fees, chargebacks, or adjustments are also applied equally to non-340B entities.

c 340B entities will not be excluded from their provider network based on criteria that are not also applied equally to non-340B entities.

d 340B entities will not be required to include any special modifiers on claims to identify 340B drugs. Claim requirements shall be the same for 340B and non-340B entities.

Unless otherwise prohibited by Law, the parties agree that an electronic copy of a signed contract, or an electronically signed contract, has the same force and legal effect as a contract executed with an original ink signature. The term “electronic copy of a signed contract” refers to a transmission by facsimile, electronic mail, or other electronic means of a copy of an original signed contract in a portable document format.

This Addendum constitutes the entire and complete understanding between the parties regarding the subject matter hereof and supersedes all previous discussions, representations, proposals, offers, counteroffers, and writings between the parties that may have occurred before entering into this Addendum.

In the event that any statute referenced herein is amended, superseded, or otherwise modified by legislative or regulatory action of the State of Vermont, such modified or successor statute shall govern and control to the fullest extent permitted by law.

WEST VIRGINIA STATE ADDENDUM
TO THE NAVITUS PARTICIPATING PHARMACY AGREEMENT

This West Virginia State Addendum to the Navitus Participating Pharmacy Agreement ("Addendum") ") applies to the extent that Participating Pharmacy dispenses outpatient prescriptions and drug products and provides pharmaceutical services to Members of a Payor subject to West Virginia law. All definitions used in this Addendum, which are not otherwise defined, have the meanings assigned to them in the Agreement. Both parties desire for the Agreement and the services provided thereunder to comply with all applicable Laws and regulations. This Addendum is intended to clarify the parties' responsibilities under the Laws of the State of West Virginia.

Now therefore, Navitus and Participating Pharmacy agree as follows:

1. Effectiveness of Addendum. If any provision of this Addendum conflicts with the terms or definitions of the Agreement, the terms of this Addendum will control with respect to Payors subject to West Virginia Law or regulation. To the extent that Participating Pharmacy provides Covered Pharmacy Services to Members of Payors licensed under West Virginia Law, Participating Pharmacy agrees to comply with any requirements for participation as a Participating Pharmacy in West Virginia as required by applicable Law. The terms of this Addendum will apply solely with regard to Covered Pharmacy Services provided to Members of Payors licensed as a health carrier under West Virginia Law and will not be deemed to amend the terms of the Agreement for Payors licensed in other states as a health carrier or for Covered Pharmacy Services not otherwise under the jurisdiction of the State of West Virginia, which may be covered by the requirements of other states. In the event of a conflict between the terms set forth in this Addendum and the terms set forth in the Agreement, this Addendum shall control for Covered Pharmacy Services.

2. Freedom of Consumer Choice for Pharmacy. Pursuant to the West Virginia Code § 33-51-11, Navitus shall, 60 days prior to the effective date of any pharmacy network, send notice to all pharmacies in the service area and offer them the opportunity to participate.

3. Pharmacy Manual Updates. Navitus shall use polices or manuals to augment the content of the contract with a health care provider. Navitus shall ensure that those polices or manuals contain sufficient information to allow providers to understand and comply with the content. For any new policy or manual, Navitus shall provide notice of the new policy, manual or change to each participating provider in writing not fewer than thirty (30) days prior to effective date of the policy or change where applicable.

4. 340B. The following is applicable to 340B entities:

a 340B entities will be reimbursed at the same rates as non-340B entities. Reimbursement rates for 340B entities shall not be lower than the rates for non-340B entities.

b 340B entities will not be charged any fees, chargebacks, or adjustments unless those same fees, chargebacks, or adjustments are also applied equally to non-340B entities.

c 340B entities will not be excluded from their provider network based on criteria that are not also applied equally to non-340B entities.

 Initials: _____

d 340B entities will not be required to include any special modifiers on claims to identify 340B drugs. Claim requirements shall be the same for 340B and non-340B entities.

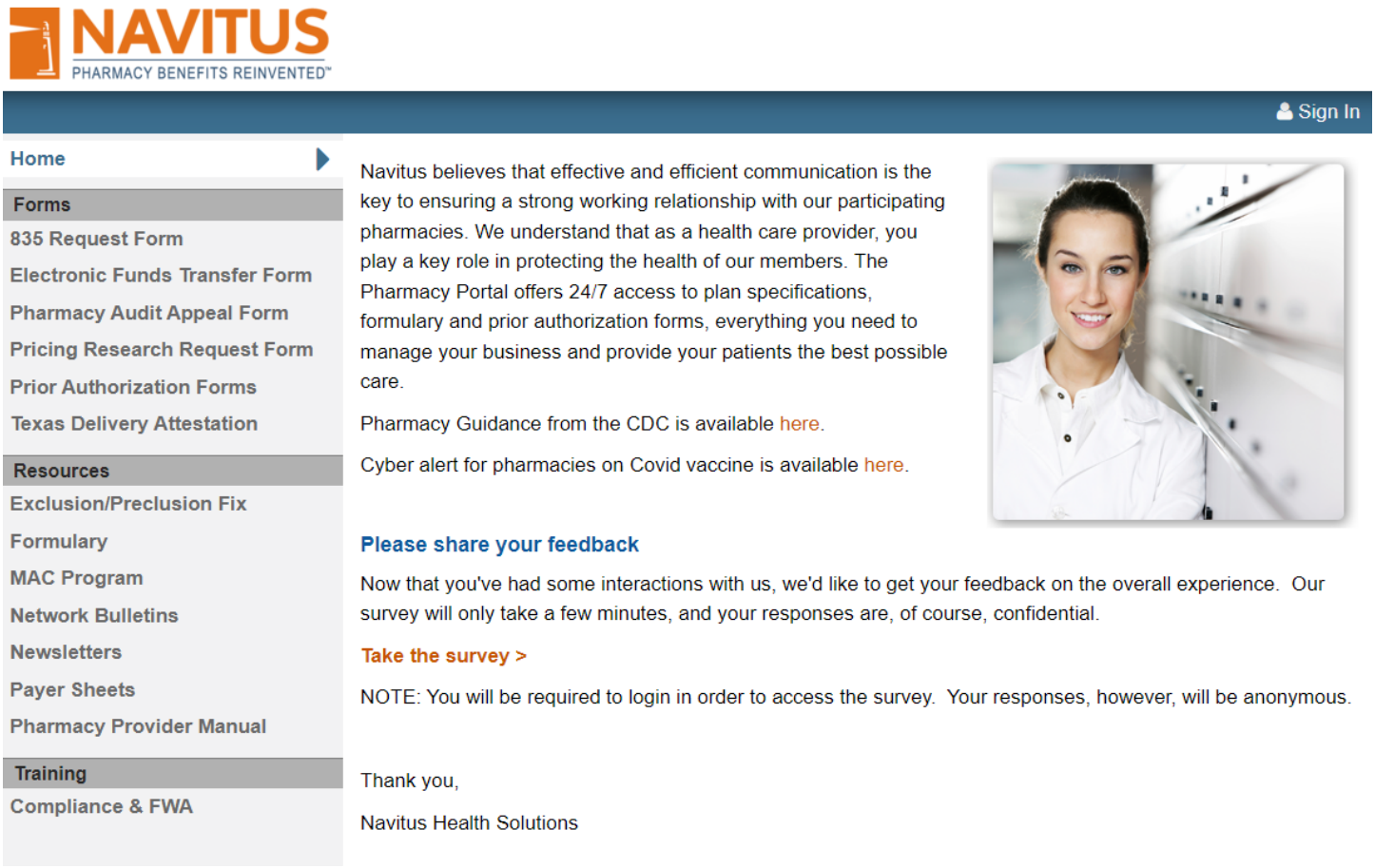
5. Dispensing Fee. Pursuant to W.VA. Code §33-51-9(f) Navitus shall not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the NADAC for the prescription drug or pharmacy service at the time the drug is administered or dispensed, plus a professional dispensing fee of $10.49.

6. This Addendum constitutes the entire and complete understanding between the parties regarding the subject matter hereof and supersedes all previous discussions, representations, proposals, offers, counteroffers, and writings between the parties that may have occurred before entering into this Addendum.

7. In the event that any statute referenced herein is amended, superseded, or otherwise modified by legislative or regulatory action by the State of West Virginia, such modified or successor statute shall govern and control to the fullest extent permitted by law.

Appendix—Navitus Documents

To access the forms listed below, log on to the Pharmacy Portal (https://pharmacies.navitus.com/Secured-Pages/Nav/home.aspx). Forms are available within the menu on the left.



- 835 Payment Request Form
    - Navitus Health Solutions will submit paper remittances to either the mailing address on file with NCPDP or what was provided on the Credentialing Application. If you would like to receive your remittances electronically (835), please return the completed 835 Payment Request Form.
- EFT Form
- Pharmacy Audit Appeal Form
- Pricing Research Request Form

Compound Claim Form

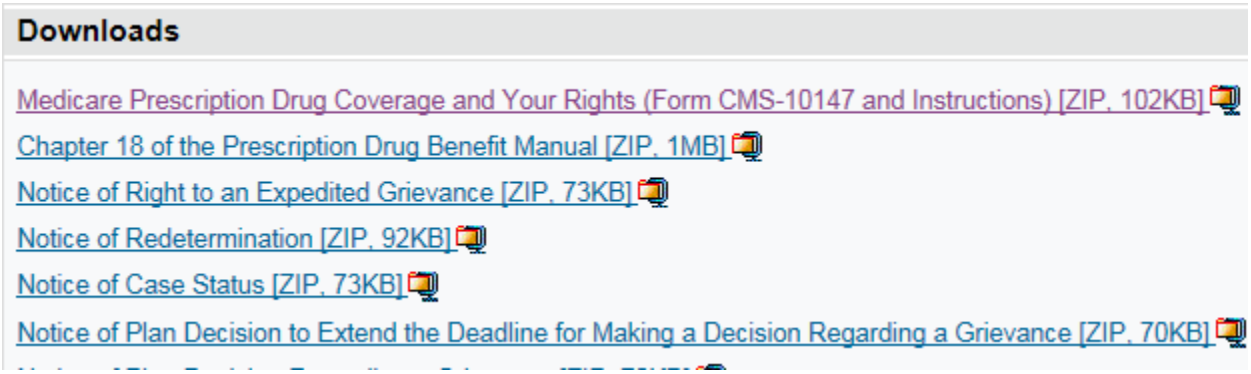
https://www.navitus.com/getdoc/d7ec4a72-e1e3-4271-a54e-1040e9272c3e/Compound-Claim-Form.aspx

Medicare Prescription Drug Coverage and Your Rights

To access the Medicare Prescription Drug Coverage and Your Rights form, go to:

https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/PlanNoticesAndDocuments.html

Scroll to Downloads to the first form:



Pharmacy Care Incentives Documentation

Clinical Services	Member Training
Pharmacy Care Incentives **Online Adjudication** **Documentation**	**Pharmacy Care Incentives** **Online Adjudication** **Documentation**
☐ Formulary Interchange Reimbursement: $4.00 NDC: 99999-9999-32	☐ Member Training on Glucose Monitors: Reimbursement: $1.00/minute up to 30 minutes Limited to 1 billing of 30 minutes per member per year NDC: 99999-9999-36
☐ Therapeutic Interchange Reimbursement: $12.00 NDC: 99999-9999-33	☐ Member Training on Asthma Inhaler/Peak Flow Meter Reimbursement: $1.00/minute up to 10 minutes Limited to 1 billing of 10 minutes per member every 6 months NDC: 99999-9999-37
☐ Change of Dose Reimbursement: $5.00 NDC: 99999-9999-34	☐ Member Training on Blood Pressure Monitors Reimbursement: $1.00/minute up to 15 minutes Limited to 1 billing of 15 minutes per member per year NDC: 99999-9999-38
☐ Member Compliance Monitoring Reimbursement: $10.00 NDC: 99999-9999-35	☐ Member Training on Nasal Inhalers Reimbursement: $1.00/minute up to 5 minutes Limited to 1 billing of 5 minutes per member every 6 months NDC: 99999-9999-39
Rx#'s from all prescriptions: _____	☐ Member Training on Insulin Reimbursement: $1.00/minute up to 20 minutes Limited to 1 billing of 20 minutes per member every 3 months NDC: 99999-9999-48
Practitioner's name: _____	Rx# from original prescription: _____
Description of change: _____	Practitioner's name: _____
Date of intervention: _____	Training time in minutes: _____
*Member signature: _____	Date of intervention: _____
	*Member signature: _____
This PCI Document is to be stored with the original hard copy and must be provided upon request. **As the pharmacy representative submitting this incentive, I attest that the service above was provided to the Member designated. I understand that this billing is also subject to audit.**	**This PCI Document is to be stored with the original hard copy and must be provided upon request.** **As the pharmacy representative submitting this incentive, I attest that the service above was provided to the Member designated. I understand that this billing is also subject to audit.**

The above form must be filled out completely and filed with the hard copy. Incentive billings are subject to audit. For a more detailed description of qualifying services, please see the Pharmacy Care Incentives section.

Rx# or #s that were involved: In most cases, this would include the Rx# of the original product prescribed and the Rx# of the product dispensed.

Practitioner's name: The name of Practitioner who authorized original order and changes to orders.

Description of change: Please include a brief explanation of the change. (e.g., Lyrica to gabapentin).

Date of intervention: Date clinical service or training was provided to Member. Reminder that PCI billing must be completed at the time the intervention was performed, not the date the prescription was filled.

*Patient signature: A signature is required for training PCI billings and preferred for clinical services. Compliance monitoring that is performed via phone should include the name of the person the pharmacy's staff spoke with and duration and date of the call.

1025W. Navitus Drive
Appleton, WI 54913

Pharmacy Audit Department
Phone: 920.221.4100
Fax: 920.221.4600
Auditing@navitus.com

Physician Verification Information

Pharmacy Name: _____ NPI: _____

Patient Information

Name:	DOB:
Address:	Phone No:
City, State, Zip:	

Physician Information

Name:	Phone No:
Address:	Fax No:
City, State, Zip:	

Prescription Information

The medication listed was prescribed with my knowledge for patient identified above by: (choose one)

1. Written 2. Telephoned 3. Electronic 4. Faxed

Rx No. _____ Date of Service: _____

Drug Name/Strength: _____

Quantity: _____ ***Total*** Fills Authorized: _____

Specific Directions: (Take as directed is not acceptable): _____

_____

Max Daily Dose (if applicable): _____ Diagnosis/Area of Application (if applicable): _____

Physician's Signature: _____Date Signed: _____
Physician's Name **(PRINT):** _____

DEA: _____or NPI: _____

Pharmacist Signature: _____ Date Signed: _____

Texas Medicaid Private-Pay Agreement

I understand _____is accepting me as a private-pay
(Provider Name)

Member for the period of _____, and I will be responsible for paying for any

Services I receive. The provider will not file a claim to Medicaid for services provided to me.

Signed: _____

Date: _____

Hennepin Health Advance Member Notice of Noncovered Prescription PDF can be found at https://edocs.dhs.state.mn.us/lfserver/Public/DHS-3641-ENG