Pharmacy Billing for Contraception

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This white paper highlights the current systemic and individual payer-based barriers to full implementation of pharmacist prescribing policies. The barriers that are analyzed include the bifurcation of medical and pharmacy benefits, complex billing technology, the perpetual need for payer guidance, and lack of clarity from agencies within the U.S. Department of Health and Human Services (HHS). This white paper also makes concrete recommendations for payment reform in order to overcome these barriers and realize the full benefit of pharmacy prescribing of contraception. Implementing these recommendations will require active participation from a range of stakeholders, including the U.S. Federal Drug Administration, the Centers for Medicare and Medicaid Services, the National Council for Prescription Drug Programs, state Medicaid agencies, state insurance commissioners, health plans, pharmacy benefit managers, pharmacies, pharmacists, and more.

Automated Pharmacy Claims

Health insurance plans rarely administer prescription drug benefits internally, and instead delegate this task out to a third party to manage enrollees' pharmacy benefits; contraception is no different. Simultaneously, claims for retail pharmacy-dispensed products, including contraception, are run through an entirely different technological system from medical claims. This system is the pharmacy claims automated decision system (ADS). Each pharmacy has its own hardware and software to run the ADS, which is unique to each payer but has a standard HIPAA-compliant format developed by the National Council for Prescription Drug Programs (NCPDP) (discussed in detail below).

The ADS approves coverage of certain drugs and services in real time. For medical benefit claims, on the other hand, coverage is not determined in real time, reimbursement can take multiple months to process, and completely different data forms are required. Ideally, **pharmacists should be able to bill for professional pharmacist services through**

either the pharmacy or medical benefit, at their discretion, depending on their practice location.[1] Requiring pharmacies to bill for contraceptive services through the medical benefit, using the CMS-1500 form, has been a significant implementation barrier.[2] Between the upfront costs to contract with medical claims administrators, the disruption to workflow from completing unfamiliar paper forms, and the uncertainty of reimbursement, retail pharmacies and the pharmacists they employ may be understandably hesitant to invest in this practice.[3] However, these hesitations are all resolved if professional pharmacist services are reimbursed directly through the pharmacy benefit.

As a general matter, states have full authority to determine the scope of the pharmacy benefit when it is the payer, i.e. Medicaid or state employee health plans.[4] State regulators, such as the department of insurance, department of managed care, or attorney general, can encourage all health plans in the state to follow suit, and as a practical matter this may make most economic sense for payers who are also responsible for Medicaid or state employee plans to streamline their processes. However, payers may not be receptive to the idea of expanding a benefit when coverage is technically already on the books. In that situation, **it may be worth exploring legislation that requires state-regulated plans to include pharmacist counseling for contraception as both a medical and pharmacy benefit**.[5]

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[1] National Council for Prescription Drug Programs, Telecommunication Version D and Above Questions, Answers And Editorial Updates (Nov. 2023), https://www.ncpdp.org/NCPDP/media/pdf/VersionD-Questions.pdf.

[2] Anu Manchikanti Gomez, *Availability of Pharmacist-Prescribed Contraception in California*, 318(22) JAMA 2253, (Dec. 2017) https://jamanetwork.com/journals/jama/fullarticle/2665763.

[3] *See* Center for American Progress, *Report: Advancing Contraception Access in States Through Expanded Pharmacist Prescribing* (Jan. 31, 2023), https://www.americanprogress.org/article/advancing-contraception-access-in-states-through-expanded-pharmacist-prescribing/.

[4] This is easiest in Medicaid fee-for-service model; it becomes more complex if the benefit is carved into managed care.

[5] For example, in 2017 New Mexico granted contraceptive prescriptive authority to pharmacists. In 2020 the state passed legislation requiring Medicaid and state-regulated commercial plans to reimburse any participating provider that is a pharmacist certified to provide a prescriptive authority service (including, but not limited to, contraceptives) at the standard contracted rate that the plan reimburses any licensed physician, physician assistant, and nurse practitioner. New Mexico House Bill 42 (2020) https://www.nmlegis.gov/Legislation/Legislation?chamber=H&legtype=B&legno=42&year=20.

National Council for Prescription Drug Programs Telecommunications Standard

The National Council for Prescription Drug Programs (NCPDP) is an independent body that, through a consensus process, develops and promotes industry standards, one of which is the Telecommunication Standard. The NCPDP Telecommunication Standard provides a universal template for automated pharmacy claims. It contains a number of standardized data fields and potential entries, and every payer has a master list of data combinations (referred to as a "payer sheet") that can be automatically approved through its pharmacy claims ADS.[6] This allows for the electronic submission of third-party drug claims and other transactions between pharmacy providers, health plans, pharmacy benefit managers (PBMs), and other third-party administrators. Generally, pharmacies should enter, and payers should require, the minimum data from the NCPDP Telecommunication Standard necessary for successful claims processing.

Under the Health Information Portability and Accountability Act (HIPAA), covered entities are required to use the NCPDP Telecommunication Standard for eligibility verification, claim and service billing, predetermination of benefits, and prior authorization for retail pharmacy transactions.[7] As a result, nearly all community pharmacies, both independent and chain, have both the hardware and software to use the NCPDP Telecommunication Standard. The current version in use by the industry is Version D.0 (vD.0), but vF6 may be adopted by CMS through administrative rulemaking.[8]

Almost all pharmacies and all intermediaries that transfer and process pharmacy claim-related information already use vD.0 for claim and service billing. Pharmacies utilize technology referred to as pharmacy management systems that encode vD.0 to submit these transactions for reimbursement on behalf of patients who have prescription drug benefits through health and/or drug plan insurance coverage. These submissions are generally routed through two intermediaries: a telecommunication switching vendor (switch) and a specialized third-party

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[6] *See* National Council for Prescription Drug Programs, NCPDP Payer Sheet Template: Implementation Guide For Version D.0 Version 17 (March 2022), https://ncpdp.org/NCPDP/media/pdf/Payer_Sheet_Template_1.pdf.

[7] 45 CFR § 162.1802.

[8] F6 was recommended by the National Committee on Vital and Health Statistics, the HHS advisory committee on health data, statistics, privacy, and national health information policy, in 2019. In 2022, CMS issued a notice of proposed rulemaking to name F6 as the HIPAA standard. 87 FR 67634 (Nov. 19, 2022), https://www.federalregister.gov/documents/2022/11/09/2022-24114/administrative-simplification-modifications-of-health-insurance-portability-and-accountability-act.

administrator for the health plan, generally a PBM. Switches validate the format of pharmacy transactions prior to transmission to the payer and then check the payer response to make sure it is formatted correctly for the pharmacy to interpret.

National Provider Identifiers

HIPAA established the national provider identifier (NPI) as the standard unique health identifier for health care providers. Health care providers can obtain an NPI from the National Plan and Provider Enumeration System, developed and operated by CMS. Organizational providers, like pharmacies, apply for and receive a Type 2 NPI; individual providers receive a Type 1 NPI and then affiliate with a Type 2 NPI to enroll as a group pharmacist prescriber. Pharmacy claims must contain a valid NPI in order to be successfully processed through the ADS.

Pharmacist prescribing of contraception occurs on a spectrum, and NPI usage varies by prescriptive authority. In fact, CMS encourages states to consider a range of pharmacy access models.[9] Collaborative practice is the most restrictive access model, requiring a formal collaborative practice agreement (CPA) with a physician or other provider. Under a CPA, it makes logical sense to use the NPI of the collaborating provider, often a physician.

The most autonomous model for pharmacist prescribing of contraception is independent prescribing, allowing pharmacists to use their clinical judgment to prescribe medications within specific categories or classes, often including over-the-counter (OTC) products. Under independent prescribing, it makes logical sense to use the NPI of the pharmacist prescriber.

In the middle of the pharmacy access spectrum are statewide protocols and standing orders, both of which enable assessment and contraceptive dispensing without the need for clinician examination or direct order from an attending provider at the time of the interaction. Despite the prevalence of standing order and statewide protocol policies, CMS expectations for submitting claims under these models are less than clear.[10] Under a standing order, a physician has authorized the medication, but a pharmacist assesses patients to determine whether the medication is appropriate for each individual patient. Should providers use the NPI of the standing order issuer or the pharmacist? A statewide protocol is authorized by a state body,

[9] Centers for Medicare and Medicaid Services, *State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols* (Jan. 17, 2017), https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf.
[10] 42 U.S.C. § 1396a(kk)(7)(B); *see also,* 42 C.F.R. §§ 431.107(b), 455.44042.

but it is not fully autonomous prescribing. Should pharmacists operating under this model apply for and use their own NPI number? As CMS has responsibility for NPIs, as well as Medicaid claims, it is in the best position to provide clarification, which is critical to provider enrollment and credentialing as well as pharmacy billing.

Product Identification

In addition to a valid NPI, pharmacy claims can only be approved through the ADS for contraceptives that are pre-programmed in using an identification system. In the NCPDP Telecommunications Standard, contraceptive products must be identified in the 407-D7 data field; the NCPDP accepts national drug codes (NDCs), universal product codes, as well as payer-specific "invented" codes in this field. **Each individual payer must have a clear list of NDCs and other accepted identification codes for the full range of contraceptives covered through the pharmacy benefit.**

National Drug Codes

The NDC number serves as a universal identifier for drugs. The NDC was introduced in 1969 and became mandatory in 1972 for all prescription and OTC drugs.[11] Each manufacturer and labeler assigns an NDC for all products that it markets; every unique combination of brand name, dosage form, strength, and package size will have its own NDC. The NDC is a 10-character code with three segments to identify the labeler, product and package, respectively. Notably, the FDA does not control assignment of the entire code, but only its first segment; product manufacturers and labelers assign the remainder of the NDC.

The FDA requires NDCs to be 10-digits. However, data field 407-D7 in the NCPDP Telecommunications Standard requires an 11-digit response without dashes. This requires some conversion, by adding a leading zero to either the 3-digit product segment or the 1-digit package segment. Payer NDC lists should provide the codes for all covered contraceptive drugs in the 11-digit NCPDP-accepted format.

In some cases, particularly for contraceptive devices, a product may not have an NDC. FDA regulations classify all single-use condoms (internal or external, with or without spermicide), the cervical cap, and contraceptive software applications as medical devices (all Class II,

[11] Linas Simonaitis & Clement J McDonald, *Using National Drug Codes and Drug Knowledge Bases to Organize Prescription Records from Multiple Sources*, 66 Am. J. Health Syst Pharm. 1743 (Oct. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2965522/.

meaning they have a moderate to high risk to the user).[12] Of note, the FDA is no longer issuing new labeler codes to medical device manufacturers, which are necessary to create NDCs. **If a pharmacist's scope of practice allows them to prescribe all self-administered contraceptives beyond hormonal products, contraceptive device identification is particularly relevant for retail pharmacy billing.** Contraceptives without an NDC can still be prescribed and processed through the pharmacy benefit with an updated ADS. In this situation, the ADS must be pre-programmed to accept alternative NCPDP-accepted codes in the 407-D7 data field, such as a unique device identifier (UDI) or a universal product code (UPC).[13]

Invented Codes

The 407-D7 data field accepts, and payer sheets can support, other non-standard product codes, also called "invented codes," for extraordinary circumstances in which an NDC, UDI, or UPC are not available.[14] South Dakota Medicaid, for example, has invented codes to be listed in the NDC field for all contraceptives on the pharmacy benefit.[15]

During the COVID-19 pandemic, NCPDP invented an 11-digit identification code in order to capture a pharmacist's patient assessment for a COVID-19 oral antiviral; this code is used in place of the NDC in data field 407-D7. NCPDP or payers could similarly create an "invented code" for a pharmacist's patient assessment for contraception. However, this would only be useful for situations in which a pharmacist's patient assessment is not associated with a dispensing event, because there is genuinely no NDC, UDI, or UPC that capture this service. In general, "invented codes" should not be used for contraceptive care at the pharmacy if an

[12] 21 CFR §§ 884. 5250–.5310, .5340, .5370. The cervical cap must be used with spermicide, aka nonoxynol-9, which is purchased separately as an FDA-regulated OTC drug, in order to be FDA-approved as a contraceptive. FDA classifies the diaphragm as a Class II medical device, but it requires in-clinic placement that is beyond pharmacist scope of practice; the diaphragm also must be used with spermicide. 21 CFR §§ 201.325, 884.5300. The contraceptive sponge, which is saturated with spermicide, is technically a drug. Intrauterine devices (IUDs) are also technically drugs, but the introducer, which assists the provider in placing the IUD, is a Class III medical device; however, IUDs, like implantable contraception, and sterilization, are beyond pharmacist scope of practice. 21 CFR §§ 310.502(a)(8), 884.5360.

[13] Final Rule, Unique Device Identification System, 78 FR 58786 (Sept. 24, 2013). The UDI must be provided in a plain-text version as well in a form that uses automatic identification and data capture technology. 21 CFR § 801.40(a).

[14] Simonaitis & McDonald, *supra* note 11.

[15] South Dakota Dept. of Social Services, *South Dakota Medicaid Billing & Policy Manual: Family Planning and Sterilization Services* (Sept. 2023), https://dss.sd.gov/docs/medicaid/providers/billingmanuals/Professional/Family_Planning.pdf.

NDC, UDI, or UPC can be used; at least on the inpatient side, invented codes result in a lot of coverage denials.[16]

Pharmacy Reimbursement

Pharmacy reimbursement is determined by the ADS based on a number of data fields submitted in the payment segment of the NCPDP Telecommunications Standard. The pharmacist task that has been least incorporated into the pharmacy claims ADS is patient assessment. In August 2022, NCPDP released guidance on patient assessment billing, stating that the most appropriate method by which a pharmacy can indicate that an assessment occurred in the NCPDP Telecommunication Standard billing claim is through the Professional Service Code (440-E5) field; pharmacies can enter the value AS (patient assessment) in this field.[17] The amount requested for the assessment should be submitted in the Incentive Amount Submitted (438-E3) field.

Over-the-Counter Dispensing Without a Prescription

Over-the-counter (OTC) drugs, sometimes called nonprescription or nonlegend drugs, are medications that can be sold directly to a consumer without a prescription from a health care professional. Many OTC drugs are available for purchase outside of a pharmacy, in locations such as convenience stores, supermarkets, vending machines, and gas stations.

In the last twenty years, more drugs that were once only available through a prescription have become available OTC. There are currently four FDA-approved contraceptives available OTC: spermicide, levonorgestrel emergency contraception (EC), and internal and external condoms. Also an OTC progestin-only birth control pill was approved by the FDA in July 2023 and is expected to be available on the market in early 2024.

Payers must facilitate OTC dispensing and coverage through clear guidance on pharmacy claims, particularly around NPIs. Payers may require the pharmacy (not the pharmacist) to put its Type 2 NPI in the service provider and prescriber fields on the point of sale transaction. This is consistent with NCPDP's guidance on billing for COVID-19 tests. CMS could also leverage its role in NPI development to facilitate OTC access by creating a Universal Provider Identifier (UPI) that pharmacists can enter for OTC transactions.

[16] Simonaitis & McDonald, *supra* note 11.
[17] National Council for Prescription Drug Programs, *supra* note 1

Conclusion

The pharmacy ADS, as applied to pharmacist prescribing of contraception, has been a barrier, highlighting the bifurcation of pharmacy and medical benefits. Overcoming this barrier will require rethinking the ADS with beneficiary-centered systems design principles in mind.[18] If stakeholders work together, pharmacist prescribing of contraception can become a functional, widespread reality.

[18] Elizabeth Edwards & David Machledt, *Principles for Fairer, More Responsive Automated Decision-Making Systems*, National Health Law Program (May 15, 2023), https://healthlaw.org/resource/principles-for-fairer-more-responsive-automated-decision-making-systems/.