

Scope of Practice and Medicaid: State Flexibility to Cover Advanced Practice Care

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Executive Summary

Advanced practice providers (APPs) are licensed health care practitioners, other than physicians, who may practice independently and bill directly under state law. Public health research supports making a variety of medications available through APPs, including medication assisted treatment, sexual and reproductive health medication, immunization, smoking cessation, and chronic care. Although APPs can function well in clinical institutions like hospitals, the greatest promise comes from embracing accessible community settings, like retail pharmacies or small outpatient clinics, to meet people where they are currently at.

While each state takes its own unique approach to licensure authority, there are two primary policy levers that impact Medicaid enrollees' access to advanced practice services: prescriptive authority and provider payment. Ideally a state would diversify its Medicaid workforce using both levers, because they work in concert to place APPs in a position to use their expanded authority.

The determination of prescriptive authority is a state one; every state has its own rules about health professions licensure, which determine the scope of practice for each licensed professional. Scope of practice rules govern what a provider can legally do in the state, but do not necessarily equate with what Medicaid will pay for. Medicaid payers are responsible for determining which clinical codes are reimbursable and in what context, and including relevant codes in provider manuals and bulletins. These determinations must comply with federal and state law, including the state Medicaid plan; however, Medicaid payers have a great deal of discretion to determine which codes are payable and to which providers.

Many of the clinical services associated with drug therapy are reimbursed as medical, rather than pharmacy, benefits under a state Medicaid plan. States could slot APP care under a number of medical benefits, both mandatory and optional. A critical consideration for states when deciding where to include APP medical benefits is the federal medical assistance percentage (FMAP). Certain benefits have an enhanced FMAP, making their inclusion low-cost for states, particularly COVID-19 testing, medication assisted treatment, and family planning.



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| I. | Introduction | 2 |
|------------|--|-----------|
| II. | Federal Medicaid Provider Standards | 4 |
| | A. State Plans | 4 |
| | B. Provider Qualifications | 5 |
| | C. Medical Assistance Definition | 6 |
| III. | Using Public Health Research to Identify Advanced Practice Care and Services | 8 |
| | A. Medication Assisted Treatment | 9 |
| | B. Sexual and Reproductive Health Medications | 11 |
| | C. Immunizations | 19 |
| | D. Smoking Cessation | 21 |
| | E. Chronic Care Devices | 21 |
| IV. | Breaking Down Advanced Practice Prescribing | 22 |
| | A. Prescriptive Authority | 23 |
| | B. Enrolling as a Medicaid Provider | 25 |
| | C. Medicaid Claims | 27 |
| | D. Procedural Terminology | 28 |
| <i>V</i> . | State Flexibility | 30 |
| | A. Prescriptive Authority | <i>30</i> |
| | B. Payment and Coding Strategies | 31 |
| | C. State Plan Options | 34 |
| | D. Federal Guidance | 39 |
| VI. | Conclusion | 40 |

This issue brief examines how Medicaid interfaces with scope of practice laws, and where states have flexibility to use an advanced practice workforce in the program. It begins with the federal rules governing who can provide care in the Medicaid program, examining the Medicaid Act's treatment of state plans, provider qualifications, and medical assistance definition. Next, the issue brief presents a non-exhaustive overview of the advanced practice care and services that public health research supports, specifically substance use disorder (SUD) treatment, sexual and reproductive health care, immunization, smoking cessation, and chronic care. It then breaks down advanced practice prescribing and how the research translates in the context of medication provision; it assesses the legal and clinical concept of prescriptive authority, enrolling and receiving payment as a Medicaid provider, submitting Medicaid claims, and relevant procedural terminology. The issue brief concludes with a review of state flexibilities to use an advanced practice workforce in Medicaid. It surveys a range of state laws on prescriptive authority and Medicaid payment, and highlights specific state plan options for expanding its prescribing workforce. It concludes with a discussion of the 2017 Centers for Medicare & Medicaid Services (CMS) informational bulletin on expanded scope of pharmacy practice and a call for additional federal guidance to facilitate meaningful implementation of advanced practice care in the Medicaid program.

I. Introduction

The federal Medicaid statute was written in 1965, and health care looked quite different at that point in time.¹ For most of the 20th century, physician-directed care was the dominant paradigm, and other providers like nurses could dispense medication but only after it was prescribed by a physician.² However, soon after the Medicaid program was up and running, a new option began to emerge: advanced practice providers (APPs).

APPs are licensed health care practitioners, other than physicians, who may practice independently and bill directly under state law. Advanced practice nurses were first officially recognized in the 1970s, and in the 1980s physician associates and nurse practitioners began pushing for limited prescribing privileges, particularly for Schedule V drugs (classified as the lowest potential for abuse among controlled substances, for example cough syrup) and "non-legend," aka over-the-counter (OTC), drugs.³ Since then, many states have expanded their

¹ The Social Security Amendments of 1965, title XIX, (codified at 42 U.S.C. §§ 1396-1–1396d.)

² Arlene W. Keeling, *Historical Perspectives on an Expanded Role for Nursing*, 20 ONLINE J. ISSUES NURSING 2 (May 2015),

https://ojin.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol-20-2015/No2-May-2015/Historical-Perspectives-Expanded-Role-Nursing.html.

³ Ass'n Advanced Prac. Psychiatric Nurses, *Political History: 1986–Present*, https://www.aappn.org/about/early-political-action (last visited Mar. 10, 2022); Am. Acad.

laws around which providers can prescribe medication within the scope of their practice licensure. In the 1990s, pharmacists successfully advocated for health insurers to pay them for non-dispensing medication services, such as consultation and drug reviews, and in the early 2000s some states granted pharmacists prescribing privileges for emergency contraception.⁴

APP expansion efforts have been met with some skepticism. Physicians may fear that they will lose regular patients, who will seek care from providers who do not know the patient's history. Patients may fear that non-physician providers do not have the training to provide high-quality medication therapy. Third-party payers may fear that they will be flooded with new claims from APPs that could strain them financially. None of these are outrageous fears.

It is true that patients might choose to use providers other than their regular physician, but they deserve the autonomy to receive care from the provider type and in the care setting of their choosing; transitions in care can also be eased by ensuring APPs have access to an updated Electronic Health Record. Patients might be wary to seek care from an APP, or may ask a lot of upfront questions about provider qualifications, but these should be easy to answer because many scope of practice laws include specific training requirements; additionally, a Cochrane review suggests that pharmacist prescribing is at least as effective as physician prescribing for acute and chronic disease management. Finally, payers may need to adapt to new claims from APPs, but this is not a negative if it reflects the true demand for these services, when they are not restricted to physicians only. And while increased preventive

Physician Assocs., *Milestones in PA History* (2017), https://www.aapa.org/wp-content/uploads/2017/01/History_Milestones.pdf. Note that "physician associates" is the preferred term within the profession, and it is used in this paper unless the referenced policy specifically uses the phrase "physician assistants."

⁴ 1996 Cal. Stat. 3030, (codified at CAL. HEALTH & SAFETY CODE § 1368.5, CAL. INS. CODE § 10125.1); 2003 Cal. Stat. 5003, (codified at CAL. BUS. & PROF. CODE § 4052(a)(10)). See also 42 U.S.C. § 1936r-8(d)(5)(B) (coverage under the Medicaid Drug Rebate Program must provide for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation).

⁵ Cochrane produces systematic review of primary research in human health care and policy. Cochrane Reviews are internationally recognized as the highest standard in evidence-based health care. G. Weeks et al., *Non-Medical Prescribing Versus Medical Prescribing for Acute and Chronic Disease Management in Primary and Secondary Care*, The Cochrane Database Syst. Rev. (2016),

https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011227.pub2/epdf/full.

care may hurt insurer profit margins in the short term, it will result in long term health benefits and cost savings.⁶

II. Federal Medicaid Provider Standards

As states are the arbiters of provider licensure, much of scope of practice policy focuses on individual state laws. However, because the Medicaid program was enacted through Congress's spending clause authority, states that choose to participate must adhere to certain federal standards. These standards apply to Medicaid in all states, and set the framework for how different providers and services are paid for under the program. The standards are broken down and examined below by state Medicaid plans, provider qualifications, and medical assistance definition.

A. State Plans

Federal medical assistance payments are made to states which have submitted, and had approved by the Secretary, a state Medicaid plan.⁷ A state Medicaid plan consists of a standardized template, issued by CMS, that includes basic program requirements as well as individualized content that reflects the characteristics of the state's program.⁸ The state plan provides assurances that a state will abide by federal rules in order to claim federal matching funds, and describes the state-specific eligibility standards, reimbursement methodologies, and program administration processes.⁹ The plan must be promptly amended to reflect material changes in federal law, state law, or program operation.¹⁰

If federal law changes, CMS issues a new state plan template and states must resubmit required information using that template. If state law changes, states must submit a state plan amendment (SPA). If a state administration wants to make significant changes in its methods and standards for setting payment rates for services, it must first provide public notice before

⁶ Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act, ASSISTANT SEC'Y FOR PLAN. AND EVALUATION (Jan. 11, 2022), https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf.

⁷ *Id.* § 1396a.

⁸ 42 C.F.R. § 430.12(a).

⁹ Medicaid and CHIP Payment and Access Comm'n, *State Plan*, https://www.macpac.gov/subtopic/state-plan/ (last visited Feb. 17, 2022).

¹⁰ 42 C.F.R. § 430.12(c).

submitting a SPA.¹¹ Note that state law might contain additional procedural and/or public notice and comment requirements.¹² SPA changes have no federal budget requirements.¹³

Once a SPA is submitted, CMS has ninety days to make a decision or the proposal automatically takes effect.¹⁴ CMS can "stop the clock" by writing to request additional information; once the state submits the requested information, a new ninety-day clock begins, but CMS may stop the clock only once per SPA application.¹⁵

SPAs that add population groups or services or increase payment rates can take effect retroactively, but the effective date: (1) cannot be earlier than the first day of the quarter in which the SPA was submitted to CMS; and (2) with respect to expenditures for medical assistance, cannot be earlier than the first day in which the SPA is in operation on a statewide basis. Once approved, a SPA does not expire, but a state can change it through a later SPA.

B. Provider Qualifications

A state plan must provide for an agreement between the Medicaid agency and each participating provider furnishing services under the plan. ¹⁸ In this agreement, participating providers agree to keep necessary records and share them on request, comply with federal regulations, furnish to the state their national provider identifier (NPI), and include their NPI on all claims submitted under the Medicaid program. ¹⁹

A state Medicaid agency must limit participation in the program to providers who accept, as payment in full, the amounts paid by the agency plus any deductible, coinsurance or copayment required to be paid by the enrollee.²⁰ Cost-sharing or similar out-of-pocket costs

¹¹ 42 C.F.R. § 447.205.

¹² Catherine McKee & Jane Perkins, *Primer: State Plan Amendments v. Section 1115 Waivers*, NAT'L HEALTH LAW PROG. (May 20, 2021), https://healthlaw.org/wp-content/uploads/2021/06/Primer-on-SPA-v.-1115-FINAL.pdf.

¹³ *Id.* at 3.

¹⁴ 42 C.F.R. § 430.16.

¹⁵ *Id.*

¹⁶ 42 U.S.C. § 430.20(b)(1).

¹⁷ McKee & Perkins, *supra* note 12, at 3.

¹⁸ 42 U.S.C. § 1396a(kk)(7)(A); 42 C.F.R. § 431.107.

¹⁹ 42 U.S.C. § 1396a(kk)(7)(B); 42 C.F.R. §§ 431.107(b), 455.44042.

²⁰ 42 C.F.R. § 447.15.

can never be charged for certain Medicaid services, like family planning, pregnancy care, and emergency services.²¹

The Health Information Portability and Accountability Act administrative simplification regulations established the NPI as the standard unique health identifier for health care providers.²² Health care providers can obtain an NPI from the National Plan and Provider Enumeration System, developed by CMS.²³ For purposes of NPIs, health care provider means

a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.²⁴

Examples of entities that do not qualify as a health care provider under this definition include veterinarians, billing services, health plans, and non-emergency transportation services.²⁵

C. Medical Assistance Definition

The federal government provides funding to each state to furnish "medical assistance," defined as the payment of part or all of the cost of certain care and services, or the care and services themselves, or both.²⁶ Each state implements this "medical assistance" through their own Medicaid program. The Medicaid statute lists the care and services that are eligible for coverage, which includes specific care and service types, care from specific providers, care in specific locations, and care furnished under specific programs (such as the Program of All-Inclusive Care for the Elderly (PACE)).²⁷

The statute lists specific care and service types that a participating state must or can cover as a part of medical assistance: laboratory and x-ray; early and periodic screening, diagnostic, and treatment (EPSDT); family planning; tobacco cessation counseling and pharmacotherapy

²¹ 42 U.S.C. §§ 13960, 13960-1.

²² 45 C.F.R. § 162.406(a).

²³ *Id.* § 162.410(b)(1).

²⁴ *Id.* § 160.103.

²⁵ CMS & Medicare Learning Network, *NPI: What You Need to Know* at 6 (March 2021), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/NPI-What-You-Need-To-Know.pdf.

²⁶ 42 U.S.C. § 1396d(a).

²⁷ *Id.*

for pregnant women; COVID-19 vaccine and administration, testing, and treatment (during the public health emergency); dental; physical and related therapies; prescription drugs; prevention and rehabilitation; hospice; case management (including primary care case management); TB-related services; personal care services; sickle cell treatment; medication assisted treatment (through Sept. 30, 2025); routine patient costs for clinical trial participation; and other medical or "remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law."²⁸

The statute also includes care and services that are provided by specific health professionals, including physicians, private duty nurses, nurse-midwives, certified pediatric nurse practitioners, and certified family nurse practitioners.²⁹ In addition, it includes care and services that occur in specific locations: hospitals (inpatient and outpatient), rural health clinics, federally-qualified health centers (FQHCs), nursing facilities, clinics under the direction of a physician, intermediate care facilities for individuals with intellectual disability, psychiatric hospitals (inpatient, for children and older adults only), freestanding birth centers, and home and community care.³⁰

Not all of these are required in the Medicaid program, but they are eligible for federal reimbursement. Originally, the only required benefits and services in the program were hospital care (inpatient and outpatient), laboratory and x-ray, nursing facility services for adults, and physicians' services.³¹ Over the years, additional care has been mandated. All remaining services are optional, although every state has chosen to cover prescription drugs.³²

²⁸ *Id.* See also § 1396d(t)(2) (defining "primary care case manager" as a physician, or, at state option, a nurse practitioner, certified nurse-midwife, or physician assistant).

²⁹ 42 U.S.C. § 1396d(a).

³⁰ *Id.*

³¹ The Social Security Amendments of 1965 § 1905, (codified at 42 U.S.C. § 1396d.)

³² Kaiser Fam. Found., *Medicaid Benefits: Prescription Drugs* (2018), https://www.kff.org/medicaid/state-indicator/prescription-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

| Mandatory Services | Optional Services | |
|--|---|--|
| -Hospital care (inpatient and outpatient)* | -Prescription drugs | |
| -Laboratory and x-ray* | -Program of All-Inclusive Care for the Elderly | |
| -Nursing facility services for adults* | -Physical therapy | |
| -Physicians' services* | -Prevention and rehabilitation | |
| -Rural health clinics | -Hospice | |
| -Federally-qualified health centers (FQHCs) | -Case management | |
| -Freestanding birth centers | -TB-related care | |
| -EPSDT for those under twenty-one | -Community supported living arrangements | |
| -Family planning | -Personal care services | |
| -Tobacco cessation and counseling for | -Sickle cell treatment | |
| pregnant women | -Private duty nursing | |
| -COVID-19 vaccine and administration, | -Physician-directed clinics | |
| testing, and treatment (through public health | -Intermediate care facilities for individuals | |
| emergency) | with intellectual disability | |
| -Medical and surgical dental | -Psychiatric hospitals (inpatient, for children | |
| -Nurse-midwife services | and older adults) | |
| -Certified pediatric nurse practitioner services | -Home and community care | |
| -Certified family nurse practitioner services | -Dental (non-medical/surgical) | |
| -Medication assisted treatment through 2025 | -Other medical or remedial care furnished by | |
| -Routine patient costs for clinical trial | licensed practitioners within the scope of | |
| participation | their practice as defined by state law | |

^{*} Required since the original Medicaid Act in 1965. All other mandatory services have been added later through Congressional amendment.

III. Using Public Health Research to Identify Advanced Practice Care and Services

Long before the COVID-19 pandemic, the health care system had been facing growing pressure to meet patient needs. Physicians report having an unreasonably short amount of time to address patient care, and patients might wait months for a doctor's appointment.³³

Scope of Practice and Medicaid

³³ Roni Caryn Rabin, *15-Minute Visits Take A Toll on the Doctor-Patient Relationship*, Kaiser Health News (Apr. 21, 2014), https://khn.org/news/15-minute-doctor-visits; Elisabeth Rosenthal, *The Health Care Waiting Game*, N.Y. Times (July 5, 2014), https://www.nytimes.com/2014/07/06/sunday-review/long-waits-for-doctors-appointments-have-become-the-norm.html.

One lever for rectifying this build-up is using an advanced practice workforce to address minor and chronic conditions that may take physician time away from a patient's chief complaint.³⁴

With an estimated seventy percent of U.S. residents taking at least one prescription drug, medication management is a common health care need.³⁵ For example, someone's insurance formulary may change, requiring a new prescription for a similar, but not therapeutically equivalent, preferred formulary medication. Or someone may exhaust their prescription refills before they can get an appointment with their doctor. These are common medication management scenarios, but they may not be a physician's priority when other patients require acute, urgent care. The good news is that medication management does not always require a physician; particularly for maintenance medications, such as birth control, public health research demonstrates that APPs are qualified to make clinical decisions about pharmacotherapy.

While advanced practice providers can function well in clinical institutions like hospitals, the greatest promise comes from embracing accessible community settings, like retail pharmacies or small outpatient clinics, to provide more convenient care. Particularly in rural areas, proximity is a major barrier.³⁶ APPs are an untapped health care resource, meeting people where they are currently at.

This section is a non-exhaustive discussion of care practices for which public health research supports using an advanced practice workforce. The following review of the evidence validates expanded use of APPs for medication assisted treatment, sexual and reproductive health medication, immunization, smoking cessation, and chronic care devices.

A. Medication Assisted Treatment

Medication-assisted treatment (MAT), which combines the use of certain medications with counseling and behavioral services, is considered the gold standard of treatment for opioid use

Truls Østbye et al., *Is There Time for Management of Patients with Chronic Diseases in Primary Care?*, 3 Annals Fam. Med. 209 (May 2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1466884.

³⁵ Mayo Clinic News Network, *Nearly 7 in 10 Americans Take Prescription Drugs* (June 19, 2013), https://newsnetwork.mayoclinic.org/discussion/nearly-7-in-10-americans-take-prescription-drugs-mayo-clinic-olmsted-medical-center-find/.

³⁶ See, e.g., Rural Health Info. Hub, *Health Access in Rural Communities*, https://www.ruralhealthinfo.org/topics/healthcare-access (last visited Mar. 10, 2022).

disorders (OUD), which account for nearly half of overdose deaths in the U.S. each year.³⁷ MAT is highly effective in reducing the rate of relapse, reducing engagement in risky activities, reducing the costs of treatment, and keeping people in treatment, thus reducing overdose deaths.³⁸ However, lack of access to MAT persists, and only a small minority of individuals with OUD are accessing the treatment.³⁹

One form of MAT is opioid dependency medications, like buprenorphine, methadone, and naltrexone. Medical experts agree that opioid dependency medications can be safely prescribed by APPs and have identified prescribing limitations as a barrier to treatment. 40 The National Academy of Sciences, Engineering, and Medicine has stated that methadone can be effectively delivered through an office-based medical practice setting and recommends that pharmacies, mobile medication units, and community health centers be used to serve greater numbers of patients.41

Currently, methadone can only be administered through specialty facilities known as opioid treatment programs. While buprenorphine can be prescribed in other settings, prescribing has historically been restricted by requiring physicians to treat only a limited number of patients or to apply for a waiver from the federal Drug Enforcement Agency (an "X-waiver") to treat additional patients. While HHS recently eliminated the X-waiver requirement for physicians, the barrier persists for APPs. 42 Further, while the federal Substance Use-Disorder Prevention that

use-disorder.html; Drug Pol'y Alliance, Statement on HHS' New Guidelines Removing Barriers from Doctors to Prescribe Life-Saving Medication for Opioid Use Disorder (Jan. 15, 2021),

³⁷ CDC. Opioid Overdose: Overdose Death Rates (Mar. 16, 2021). https://www.cdc.gov/drugoverdose/data/overdose.html.

³⁸ Substance Abuse & Mental Health Servs. Admin., *Medication-Assisted Treatment (MAT)* (Nov. 29, 2021), https://www.samhsa.gov/medication-assisted-treatment.

³⁹ Substance Abuse & Mental Health Servs, Admin., Medicaid Coverage of Medicaid-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose 6 (2018),

https://store.samhsa.gov/sites/default/files/d7/priv/medicaidfinancingmatreport 0.pdf.

⁴⁰ U.S. Gov't Account. Office, Opioid Use Disorder: Barriers to Medicaid Beneficiaries' Access to Treatment Medications 21 (Jan. 2020), https://www.gao.gov/assets/gao-20-233.pdf.

⁴¹ COMM. ON MEDICATION-ASSISTED TREATMENT FOR OPIOID USE DISORDER, NAT'L ACADS. OF SCIS., ENG'G & Med., Medications for Opioid Use Disorder Save Lives 10 (Alan I. Lesgner & Michelle Mancher eds., 2019), https://www.ncbi.nlm.nih.gov/books/NBK538936/pdf/Bookshelf NBK538936.pdf. ⁴² HHS, HHS Expands Access to Treatment for Opioid Use Disorder (Jan. 14, 2021), https://www.hhs.gov/about/news/2021/01/14/hhs-expands-access-to-treatment-for-opioid-

Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (the SUPPORT Act) allows other qualifying practitioners, including nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives to prescribe buprenorphine, this temporary privilege expires Oct. 1, 2023.⁴³

Another form of MAT is opioid overdose prevention medication, known as naloxone. Naloxone is an opioid antagonist that binds to opioid receptors and blocks the effect of opioids. Naloxone saves lives, but it must be administered quickly after opioid overdose begins.⁴⁴ Given the need for quick administration of the medication, research has shown that distributing naloxone to people who use drugs is an effective overdose prevention tactic because those individuals are most likely to witness an overdose and be able to administer naloxone in a timely manner.⁴⁵ In recognition of this research, all U.S. states have some form of advanced practice prescribing laws for naloxone.⁴⁶

B. Sexual and Reproductive Health Medications

Much like MAT, access to medications for sexual and reproductive health care is inhibited by increasing restrictions. The proliferation of state-level anti-abortion policies has led to the shuttering of a number of clinics employing abortion providers.⁴⁷ Expanding the ability of APPs

https://drugpolicy.org/press-release/2021/01/statement-hhs-new-guidelines-removing-barriers-doctors-prescribe-life-saving.

⁴³ The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (SUPPORT Act) § 3201, (codified at 21 U.S.C. § 823(g)(2)(G)(iii).)

⁴⁴ Substance Abuse & Mental Health Servs. Admin., *Naloxone* (July 8, 2021), https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/naloxone.

⁴⁵ Rebecca McDonald & John Strang, *Are Take-Home Naloxone Programmes Effective? Systemic Review Utilizing Application of the Bradford Hill Criteria*, 111 Addiction 1177 (2016), https://onlinelibrary.wiley.com/doi/pdf/10.1111/add.13326.

⁴⁶ Nat'l All. State Pharmacy Ass'ns, *Pharmacist Prescribing: Naloxone* (Mar. 2022), https://naspa.us/resource/naloxone-access-community-pharmacies/.

⁴⁷ Brittini Frederiksen et al., *Rebuilding Title X: New Regulations for the Federal Family Planning Program*, KAISER FAM. FOUND. (Nov. 3, 2021), https://www.kff.org/womens-health-policy/issue-brief/rebuilding-title-x-new-regulations-for-the-federal-family-planning-program/ (citing Office of Pop. Affairs, *Title X Family Planning Annual Report, 2020 National Summary* (Sept. 2021), https://opa.hhs.gov/sites/default/files/2021-09/title-x-fpar-2020-national-summary-sep-2021.pdf) (describing how the Trump Administration's 2019 Title X regulations,

to deliver sexual and reproductive health medications, including in non-clinical settings, could help fill the increasingly large gap in care.

1. Contraception

Governing bodies and professional medical organizations have long held that contraception can safely be prescribed by APPs. Notably, the federal Title X program allows family planning services to be directed by a range of providers, which could "include[] physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice and who are trained and permitted by state-specific regulations to perform comprehensive contraceptive care."⁴⁸ Even more expansively, the American College of Obstetricians and Gynecologists (ACOG) supports OTC access to hormonal contraception, while recognizing that pharmacist-provided contraception may be a necessary intermediate step. ⁴⁹ Similarly, ACOG states that no clinical examination or pregnancy testing is necessary before prescribing emergency contraception (EC) and that it should be administered as soon as possible when needed. ⁵⁰

Many states require Medicaid beneficiaries to have a prescription in order to access contraception, even OTC contraception.⁵¹ As of 2021, thirty of the thirty-six state Medicaid programs that covered OTC contraception required a prescription.⁵² Similarly, of the thirty-five states that cover emergency contraception, twenty-seven require a prescription. This is likely because states can only obtain federal dollars under the Medicaid Drug Rebate Program for

in addition to the pandemic, reduced the number of clients served for family planning services from 3.9 million to 1.5 million people).

⁴⁸ 42 C.F.R. §§ 59.2, 59.5.

⁴⁹ ACOG, *Committee Opinion No. 788: Over-the-Counter Access to Hormonal Contraception* (Oct. 2019), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/over-the-counter-access-to-hormonal-contraception.

⁵⁰ ACOG, *Practice Bulletin No. 152: Emergency Contraception* (Sept. 2015), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2015/09/emergency-contraception.

⁵¹ See Abigail Coursolle & Liz McCaman Taylor, Coverage of Over-the-Counter Drugs in Medicaid, NAT'L HEALTH L. PROG. (Feb. 1, 2022), https://healthlaw.org/wp-content/uploads/2019/12/2022-02-08-OTC-Drugs-in-Medicaid-Final-REV-2022-2.pdf.

⁵² Kaiser Fam. Found., *Medicaid Coverage of Family Planning Benefits: Findings from a 2021 State Survey* (Feb. 2022), https://files.kff.org/attachment/medicaid-coverage-of-family-planning-benefits-findings-from-a-2021-state-survey.pdf.

OTC drugs if they are prescribed.⁵³ While the evidence supports OTC access to hormonal contraception, if prescription requirements remain then APP prescribing is crucial; authorizing APPs to prescribe contraception would increase access to prescribers as well as allow for affordability through insurance coverage.⁵⁴

2. Sexually Transmitted Infection Prevention

Recently, the Food & Drug Administration (FDA) authorized the marketing of the first condoms specifically indicated to help reduce transmission of sexually transmitted infections (STIs) during anal intercourse. These external condoms, which will be called the One Male Condom, are also indicated as a contraceptive and can help reduce the transmission of STIs during vaginal intercourse. This authorization opens the door for other condom manufacturers to market their products for STI prevention during anal intercourse if they can demonstrate substantial equivalence to the One Male Condom.

While the One Male Condom website does not provide any information on insurance coverage or reimbursement, an APP could potentially prescribe the product for pregnancy and/or STI prevention.⁵⁸ Additionally, updates to the Women's Preventive Services Guidelines that take effect on Jan. 1, 2023 eliminate the gendered language surrounding condoms as a contraceptive, leaving open the possibility that the One Male Condom and other external condoms will be covered under the Affordable Care Act's (ACA's) preventive services requirement.⁵⁹

⁵³ Coursolle & McCaman Taylor, *supra* note 51, at 2; *see also* Pamela Schweitzer & Mark Atalla, *Medicaid Reimbursement for Pharmacist Services: A Strategy for the Pharmacy Profession*, 78 Am. J. Health-Syst. Pharm. 408, 412 (2021).

⁵⁴ Krisha K. Upadhya, *Over-the-Counter Access to Oral Contraceptives for Adolescents*, 60 J. ADOLESCENT HEALTH 634 (2017).

⁵⁵ FDA, FDA Permits Marketing of First Condom Specifically Indicated for Anal Intercourse (Feb. 23, 2022), https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-condom-specifically-indicated-anal-intercourse.

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ ONE Condoms, *Where to Buy*, https://www.onecondoms.com/pages/where-to-buy (last visited Mar. 10, 2022); ONE Condoms, FAQ, https://www.onecondoms.com/pages/faq (last visited Mar. 10, 2022).

The ACA requires most private health insurance plans to cover preventive care and screening services for women identified in comprehensive guidelines supported by the Health Resources & Services Administration. *See* 42 U.S.C. § 300gg-13(a)(1)–(4); Health Res. & Servs. Admin., *Women's Preventive Services Guidelines*, https://www.hrsa.gov/womens-guidelines (last visited Mar. 10, 2022).

3. Pre- and Post-Exposure Prophylaxis

Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are medications used to prevent and treat HIV, respectively. PrEP is a daily medication for people at risk of contracting HIV from either sex or injection drug use. PrEP is highly effective; when taken every day, it reduces the risk of contracting HIV by ninety-nine percent. PEP is an antiretroviral drug used to prevent HIV <u>after</u> a high-risk event, such as unprotected sex or needle sharing.

While these medications represent groundbreaking advancements in HIV prevention, data shows that progress has stalled, in part because these medications are not yet widely used. According to 2019 CDC data, only twenty-three percent of people eligible for PrEP were prescribed it; this is a significant improvement from 2015, when that rate was three percent, but still leaves the majority of potential PrEP users without a prescription. Further, African Americans are more than eight times more likely and Hispanics/Latinos are almost four times more likely than whites to contract HIV, largely because they face barriers accessing prevention services. Fig. 1.

State Medicaid programs are required to cover all FDA-approved medications from manufacturers that have entered into federal rebate agreements, meaning that antiretroviral medications like PrEP and PEP are covered;⁶² however, PrEP and PEP treatment includes more than just administering the medication; testing and counseling are also essential to the course of treatment.⁶³ Enabling a broader range of providers to administer PrEP and PEP and related treatment would significantly increase access, particularly providers who are located in

⁶⁰ CDC, *2019 National HIV Surveillance System Reports* (May 27, 2021) https://www.cdc.gov/nchhstp/newsroom/2021/2019-national-hiv-surveillance-system-reports.html.

⁶¹ *Id.* Note that the terms "African Americans" and "Hispanics/Latinos" are used here to mirror the CDC data.

^{62 42} U.S.C. § 1396r-8.

⁶³ The Center for Consumer Information and Insurance Oversight (CCIIO) within CMS has clarified, for example, that preventive PrEP care encompasses anti-retroviral medications as well as routine testing and counseling. CCIIO, *FAQs About Affordable Care Act Implementation Part 47* (July 19, 2021), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-47.pdf.

community pharmacies or community-based health settings. Further, the CDC has recommended expanding the use of telehealth for PrEP initiation.⁶⁴

In 2020 California enacted SB 159, which permits pharmacists to dispense PrEP and PEP without a prescription and connect individuals to physicians for long term care; similar efforts are underway in Colorado, Illinois, and Maryland.⁶⁵ Some state Medicaid programs also reimburse pharmacists for enhanced medication therapy management services.⁶⁶ Extending eligibility for these services to PrEP patients would improve care coordination for Medicaid enrollees.⁶⁷

4. Abortion

Mifepristone, taken along with misoprostol, is a two-drug combination known as medication abortion.⁶⁸ The latest data show that in 2020, medication abortion accounted for fifty-four percent of US abortions.⁶⁹ Historically, patients could only receive medication abortion from specific certified providers and only in person, even when counseling can be delivered via telehealth and patients can administer the medications on their own.⁷⁰

⁶⁹ *Id.*

⁶⁴ CDC, *US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline* 40 (Dec. 2021), https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.

⁶⁵ 2019 Cal. Stat. 88, (codified at Cal. Bus. & Prof. Code §§ 4052(a)(10), 4052.02, 4052.03); Colo. Rev. Stat. §§ 12-280-103, 12-280-125.7, 25-1-130; H.B. 4430, 102nd Gen. Assemb., Reg. Sess. (Ill. 2022) (amending 225 Ill. Comp. Stat. 85/3(d)(14, adding 225 Ill. Comp. Stat. 85/43.5)((at the Governor's desk for signature as of Apr. 20, 2022); S.B. 355, 2022 Leg., 444th Sess. (Md. 2022) (amending Md. Code Ann., Health Occ. § 12-101).

⁶⁶ CDC, *Pharmacist-Provided Medication Therapy Management in Medicaid* (May 2021), https://www.cdc.gov/dhdsp/docs/MTM in Medicaid-508.pdf.

⁶⁷ See Naomi Seiler, Issue Brief: Leveraging Medicaid Financing and Coverage Benefits to Deliver PrEP Intervention Services, ACAD. HEALTH (May 2019),

https://academyhealth.org/sites/default/files/financingmedicaidprep_issuebrief_may2019.pdf.

⁶⁸ Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, Guttmacher Inst. (Feb. 2022),

https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

⁷⁰ Fabiola Carrión & Madeline Morcelle, *Win for Abortion Access During COVID19 (And Hopefully Beyond?)*, NAT'L HEALTH L. PROG. (July 24, 2020), https://healthlaw.org/win-for-abortion-access-during-covid19-and-hopefully-beyond/.

Recently, the FDA permanently lifted some restrictions on mifepristone, in particular the requirement that the medication be administered in-person.⁷¹ Certified pharmacies can now dispense medication abortion.⁷² This move was celebrated by ACOG, who stated that there "is no safety reason for the restrictions" and that the prior in-person requirement "d[id] nothing to bolster the safety of an already-safe medication."⁷³ To facilitate this change, states should reexamine their bundled payments for medication abortion and ensure mifepristone and misoprostol are included in the Medicaid pharmacy benefit so that pharmacies can successfully dispense.

Under the current FDA protocol, providers must become certified to prescribe mifepristone and confirm that they have the ability to date pregnancies accurately, diagnose ectopic pregnancies, and provide any necessary surgical intervention or make arrangements for others to provide such care. Notably, the restrictions do not limit prescriptive authority for medication abortion to physicians only; they acknowledge that some states allow non-physician providers to prescribe, and advise providers to check individual state laws. Currently, pharmacists may be able to prescribe medication abortion under a collaborative practice agreement, and states may consider examining their scope of practice laws to allow pharmacists more autonomous prescribing privileges for medication abortion.

Unfortunately, thirty-two states continue to limit abortion medication administration to physicians only, and nineteen require in-person prescribing.⁷⁶ These requirements run counter to the evidence that mifepristone can be safely prescribed without any special restrictions.⁷⁷ Several major medication associations, including the World Health Organization, American Public Health Association, American Medical Women's Association, and ACOG, have all argued

⁷¹ FDA, *Questions and Answers on Mifeprex* (updated Dec. 16, 2021), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex.

⁷² *Id.*

⁷³ ACOG, *ACOG Applauds the FDA for it Action on Mifepristone Access During the COVID-19 Pandemic* (Apr. 2021), https://www.acog.org/news/news-releases/2021/04/acog-applauds-fda-action-on-mifepristone-access-during-covid-19-pandemic.

⁷⁴ FDA, *Questions and Answers on Mifeprex*, *supra* note 71.

⁷⁵ *Id.*

⁷⁶ Guttmacher Inst., *Medication Abortion* (Jan. 1, 2022), https://www.guttmacher.org/state-policy/explore/medication-abortion.

⁷⁷ Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 N. ENGL. J. MED. 57 (2022), https://www.nejm.org/doi/full/10.1056/NEJMsa2109779.

that APPs should be authorized to provide medication abortion.⁷⁸ In line with these recommendations, a third of states permit some APPs to independently provide medication abortion.⁷⁹ Expanding these practices to additional qualified providers, such as pharmacists, has the potential to increase access to abortion care.

5. Prenatal Vitamins

Folic acid, which is often included in prenatal vitamins, has been shown to prevent neural tube defects in a developing fetus; women who are planning or capable of pregnancy receive substantial benefit from daily supplementation.⁸⁰ State Medicaid programs must cover nonprescription prenatal vitamins.⁸¹ However, they have significant leeway to implement utilization controls.

While only four states (Alaska, Colorado, Connecticut, and New York) report requiring a prescription for prenatal vitamins, the true number may be higher if states are seeking federal reimbursement under the Medicaid Drug Rebate Program.⁸² Connecticut reports that individuals under age twenty-one can access prenatal vitamins OTC, which may indicate that reimbursement is coming through the EPSDT benefit rather than the prescription drug benefit.⁸³ Similar to OTC contraception, authorizing APPs to prescribe prenatal vitamins could increase affordability by ensuring insurance coverage for nonprescription products.

⁷⁸ Heather D. Boonstra, *Medication Abortion Restrictions Burden Women and Providers— and Threaten U.S. Trend Toward Very Early Abortion*, 16 GUTTMACHER POL'Y REV. 18, 19-20 (2013), https://www.guttmacher.org/gpr/2013/03/medication-abortion-restrictions-burden-women-and-providers-and-threaten-us-trend-toward.

⁷⁹ UCSF Bixby Ctr. for Glob. Reprod. Health, *State Abortion Laws and Their Relationship to Scope of Practice*, https://aptoolkit.org/advancing-scope-of-practice-to-include-abortion-care/state-abortion-laws-and-their-relationship-to-scope-of-practice/ (last visited Apr. 29, 2022).

⁸⁰ U.S. Preventive Servs. Task Force, *Folic Acid for the Prevention of Neutral Tube Defects: Preventive Medication* (Jan. 10, 2017),

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/folic-acid-for-the-prevention-of-neural-tube-defects-preventive-medication.

^{81 42} U.S.C. § 1396r-8(d)(2)(E).

 ⁸² Id. See also Kathy Gifford et al., Medicaid Coverage of Pregnancy and Perinatal Benefits: Results from a State Survey, KAISER FAMILY FOUND. 17 (April 27, 2017), https://files.kff.org/attachment/Report-Medicaid-Coverage-of-Pregnancy-and-Perinatal-Benefits; Coursolle & McCaman Taylor, supra note 51, at 2.
 ⁸³ Gifford, supra note 82.

Scope of Practice and Medicaid

6. Gender-Affirming Care

LGBTQ+ individuals already face a wide range of health care disparities, including discrimination, denials of care, lack of competent and affirming providers, and lack of insurance.⁸⁴ A first-of-its-kind national survey of LGBTQ individuals about their health care experiences found that fifty percent of transgender respondents had to teach their medical providers about transgender care because their doctors were uninformed.⁸⁵

Transgender individuals face difficulties accessing gender-affirming care (such as mental health services, hormone therapy, or transition-related surgery) in particular. A recent survey by the Center for American Progress found that fifty-five percent of transgender individuals reported needing to travel at least ten miles in order to receive transition-related care, which made it impossible to access for many.⁸⁶ And now a record number of states are seeking to actively prevent gender-affirming care for transgender and gender non-conforming individuals.⁸⁷

In addition, many transgender individuals struggle to access gender-affirming care due to lack of insurance coverage, particularly among Medicaid enrollees. As of 2019, only eighteen states plus Washington D.C. include coverage for gender-affirming care under their Medicaid

⁸⁴ Lambda Legal, *When Health Care Isn't Caring* 5, 9–10 (2014), https://www.lambdalegal.org/publications/when-health-care-isnt-caring; Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AM. PROGRESS (Jan. 18, 2018), https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/; Sharita Gruberg, *An Effective Response to the Coronavirus Requires Targeted Assistance for LGBTQ People*, CTR. FOR AM. PROGRESS (April 9, 2020), https://www.americanprogress.org/issues/lgbtq-rights/news/2020/04/09/482895/effective-response-coronavirus-requires-targeted-assistance-lgbtq-people/.

⁸⁵ Lambda Legal, *supra* note 84, at 6.

⁸⁶ Caroline Medina et al., *Protecting and Advancing Health Care for Transgender Adult Communities*, CTR. FOR AM. PROG. (Aug. 18, 2021), https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-

<u>adult-communities/</u>.

⁸⁷ See Freedom for All Americans, Legislative Tracker: Youth Healthcare Bans, https://freedomforallamericans.org/legislative-tracker/medical-care-bans/ (last visited Mar. 10, 2022); see also Abigail Coursolle, Skyler Rosellini, & Cathren Cohen, Gender-Affirming Care for Youth is Still Good Health Care, NAT'L HEALTH L. PROG. (Jan. 31, 2022), https://healthlaw.org/gender-affirming-care-for-youth-is-still-good-health-care/.

programs, while twelve states had explicitly excluded coverage for such care (twenty states did not address coverage).⁸⁸

Another barrier to care is the historical requirement that a patient receive a letter from a mental health provider before initiating hormone therapy. However, medical experts have determined that this interim step is unnecessary if the hormone provider is also qualified to assess gender dysphoria. The seventh version of the World Professional Association for Transgender Health (WPATH) standards of care states that hormone therapy can be initiated by any "qualified health professional" who "feel[s] comfortable making an assessment and diagnosis of gender dysphoria, as well as assessing for capacity to provide informed consent." In addition, the WPATH standards of care indicate that prescribing genderaffirming hormones is well within the scope of practice for a range of APPs, including advanced practice nurses and physician assistants. Allowing APPs to prescribe and administer gender-affirming hormone therapy, as well as embracing telemedicine, can help to improve access to this treatment.

C. Immunizations

APPs can safely and effectively prescribe and administer a wide range of immunizations, including hepatitis A and B, herpes zoster, human papillomavirus, Japanese encephalitis, meningitis, pneumococcal disease, rabies, tuberculosis, typhoid, varicella, yellow fever, and more. As of 2016, eighteen states allow nurse practitioners to prescribe vaccines under their

⁸⁸ Christy Mallory & William Tentindo, *Medicaid Coverage for Gender-Affirming Care*, WILLIAMS INST. (Oct. 2019), http://williamsinstitute.law.ucla.edu/wp-content/uploads/Medicaid-Gender-Care-Oct-2019.pdf.

⁸⁹ Madeline B. Deutsch, *Initiating Hormone Therapy*, UCSF TRANSGENDER CARE (June 17, 2016), https://transcare.ucsf.edu/guidelines/initiating-hormone-therapy.

⁹⁰ *Id.*; World Pro. Ass'n for Transgender Health (WPATH), *Standards of Care V7* at 33–36 (2011),

https://www.wpath.org/media/cms/Documents/SOC%20v7/Standards%20of%20Care%20V7 %20-%202011%20WPATH.pdf. Note that the eighth version of the WPATH Standards of Care was under review and public comment at the time of this writing and is expected to be published later in 2022.

⁹¹ WPATH, Standards of Care V7, supra note 90, at 41, 46.

⁹² Lil Kalish, *Is Trans Telehealth the Future—or Just a Cash Grab?*, MOTHER JONES (July 8, 2021), https://www.motherjones.com/politics/2021/07/is-trans-telehealth-the-future-or-just-a-cash-grab/.

own authority, and an additional thirty-one allow upon delegated authority. ⁹³ All fifty states allow physician assistants to prescribe immunizations upon delegated authority. ⁹⁴ Thirty states allow midwives to prescribe immunizations upon delegated authority, and seventeen upon their own authority. ⁹⁵

Standardized training on immunization is included in pharmacy degree programs, and both the CDC and the National Vaccine Advisory Committee endorse pharmacist immunization practices. ⁹⁶ Before the COVID-19 pandemic, pharmacists in eighteen states had authority to prescribe at least one immunization. ⁹⁷ In light of the public health emergency, both the federal and state governments acted to expand pharmacist scope of practice for COVID-19 vaccination. The federal Public Readiness and Emergency Preparedness (PREP) Act authorizes state-licensed pharmacists to order and administer COVID-19 therapeutics, following a practical training program. ⁹⁸ This Act preempted state scope of practice requirements. ⁹⁹

Since the pandemic began, over 100 bills have been introduced across thirty-two states to expand scope of practice to include vaccine administration for a variety of providers, including pharmacists, pharmacy technicians, dentists, optometrists and EMTs.¹⁰⁰ The successful expansion of the scope of providers delivering COVID-19 immunizations concretely demonstrates that APPs can be trusted to prescribe and administer vaccines.

⁹³ Alexandra M. Stewart, *State Late and Standing Orders for Immunization Services*, 60 Am. J. PREV. MED 133 (May 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4841732/.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ Sharon Xavioer & Jeff Goad, *Authority and Scope of Practice: How States Differ*, Pharmacy Times (June 22, 2017), https://www.pharmacytimes.com/view/authority-and-scope-of-vaccination-how-states-differ.

⁹⁷ Nat'l All. State Pharmacy Ass'ns, *Statewide Protocol Infographic* (May 29, 2018), https://naspa.us/resource/statewide-protocols-for-pharmacist-prescribing/.

⁹⁸ U.S. Asst. Sec. for Preparedness & Response, *Expanding Access to COVID-19 Therapeutics: HHS PREP Act Declaration: 9th Amendment* (Sept. 8, 2021), https://www.phe.gov/Preparedness/legal/prepact/Documents/PrepAct-Declaration-Amendment-FactSheet-8sept2021.pdf.

⁹⁹ *Id.*

¹⁰⁰ Maggie Davis & Adrianna Evans, *Who Are the Vaccinators? A Look at the Vaccination Workforce*, Ass'n State & Territorial Health Offs. (Apr. 21, 2021), https://www.astho.org/communications/blog/a-look-at-the-vaccination-workforce/.

D. Smoking Cessation

Prescription medications can assist in smoking cessation by reducing withdrawal symptoms, reducing pleasure from smoking, or reducing cravings. ¹⁰¹ Studies have found that smoking cessation programs delivered through trained community pharmacists with prescriptive authority are an effective approach to reduce smoking and increase access to these services. ¹⁰² New Mexico led the way on access to tobacco cessation medication, enacting legislation in 2001 that allowed for pharmacist prescribing. ¹⁰³ The State's protocol for tobacco cessation includes "all FDA approved products for tobacco cessation," including nicotine replacement products, Chantix and Zyban. ¹⁰⁴ Since then, five additional states (California, Idaho, Arizona, Maine, Colorado) have similarly expanded pharmacist scope of practice for these medications. ¹⁰⁵

E. Chronic Care Devices

Individuals with chronic conditions, such as diabetes or asthma, often use medical supplies, equipment and appliances to manage their conditions. Medical supplies are health related items that are consumable or disposable, like blood sugar test strips, needles, lancets, catheters, and incontinence pads. Medical equipment and appliances, on the other hand, can withstand repeated use, can be reusable or removable, and are generally not useful in the absence of a disability, illness or injury. Examples include insulin pumps, glucose monitors, metered dose inhalers and spacer devices, nebulizers, peak flow meters, canes, walkers, and wheelchairs.

¹⁰¹ Am. Cancer Soc'y, *Prescription Medications to Help You Quit Tobacco* (Oct. 10, 2020), https://www.cancer.org/healthy/stay-away-from-tobacco/guide-quitting-smoking/prescription-drugs-to-help-you-quit-smoking.html.

¹⁰² See Nasreen Khan et al., Smoking Cessation and Its Predictors: Results from a Community-Based Pharmacy Tobacco Cessation Program in New Mexico, 36 Annals Pharmacotherapy 11986 (2012), https://pubmed.ncbi.nlm.nih.gov/22911338/; Xian Shan et al., Quitting Patterns and Predictors of Success Among Participants in a Tobacco Cessation Program Provided by Pharmacists in New Mexico, 20 J. Managed. Care & Specialty Pharmacy 579 (2014), https://pubmed.ncbi.nlm.nih.gov/24856596/.

¹⁰³ N.M. CODE R. § 16.19.26.14.

¹⁰⁴ Nat'l All. State Pharmacy Ass'ns, *Pharmacists Authorized to Prescribe Tobacco Cessation Therapy in More States* (June 23, 2017), https://naspa.us/2017/06/pharmacists-authorized-to-prescribe-tobacco-cessation-therapy-in-more-states/.

¹⁰⁵ *Id.*

¹⁰⁶ 42 C.F.R. § 440.70(b)(3).

¹⁰⁷ *Id.*

Medical supplies and equipment are generally available in the commercial market without any provider authorization, but paying for these out of pocket can be financially burdensome and impede continuous use.¹⁰⁸ For this reason, enrollees may look to insurance coverage for financial relief. While getting medical supplies and equipment through insurance can ease financial burden, it likely adds administrative burden, including the ongoing need to get a home health order from a qualified provider. States vary as to whether APPs are authorized to issue such orders under their licensed scope of practice.¹⁰⁹

IV. Breaking Down Advanced Practice Prescribing

Given the research in support of advanced practice prescribing, the next step in using this workforce is answering the following: Who is allowed to issue a prescription, and will Medicaid pay them for the clinical encounters surrounding the issuance of a prescription?

The determination of prescriptive authority is a state one; every state has its own rules about health professions licensure, which determine the scope of practice for each licensed professional. Scope of practice laws fall along a spectrum from collaborative to autonomous prescribing models. These laws allow different health professionals, including both physicians and APPs, to prescribe drugs. These laws do not typically delve into the specific clinical tasks surrounding the issuance of prescription drugs; this is determined by standard of care and translated into procedural terminology. Providers render a myriad of baseline and monitoring services in conjunction with prescribing, and each service corresponds with a current procedural terminology (CPT) code to document care. Medicaid payers, either the state Medicaid agency or Medicaid managed care entity, are responsible for surveying all CPT codes, determining which codes are reimbursable and in what context, and including relevant codes in provider manuals and bulletins. These determinations must comply with federal and state laws, including the state Medicaid plan; however, Medicaid payers have a great deal of discretion to determine which codes are payable and to which providers.

¹⁰⁸ See Marguerite E. Burns et al., Living at the Thin Margin of Health: Out-of-Pocket Health Care Spending by Medicaid Beneficiaries with Disabilities, 29 HEALTH AFFS. 1517 (Aug. 2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2936779/.

¹⁰⁹ See Susan Jaffe, Home Health Care Providers Struggle with State Laws and Medicare Rules as Demand Rises, 38 HEALTH AFFS. 981 (June 2019), https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2019.00529.

¹¹⁰ Nat'l Conf. State Legislatures, *Scope of Practice Overview*, Scope of Practice Policy, https://scopeofpracticepolicy.org/practitioners-overview/.

A. Prescriptive Authority

When thinking about prescribers, historically this has referred to physicians. Currently, those with Doctor of Medicine or Doctor of Osteopathic Medicine credentials have the broadest prescriptive authority. Many other health professionals have independent prescriptive authority related to their area of practice. Veterinarians, podiatrists, and dentists have prescribing power in all fifty US states and DC (although veterinarians do not qualify for an NPI and therefore cannot request Medicaid reimbursement). Optometrists prescribe medications to treat certain eye diseases, and also issue spectacle and contact lens prescriptions for corrective eyewear. Several US states have passed legislation allowing clinical psychologists who are registered as medical psychologists and have undergone specialized training to prescribe drugs to treat emotional and mental disorders. Some states also allow naturopathic doctors a limited scope of prescriptive authority.

Additionally, all states and DC grant physician associates, registered certified nurse practitioners, and other advanced practice registered nurses, such as nurse-midwives, independent prescriptive authority, although some states restrict their prescribing of controlled substances. ¹¹⁶

Pharmacists have prescriptive authority in some states through collaborative or autonomous prescribing.¹¹⁷ Collaborative prescribing requires a formal collaborative practice agreement (CPA) with a physician or other provider that allows them to delegate certain patient care functions to the pharmacist; it can be used broadly for the treatment of acute or chronic disease.¹¹⁸ CPAs can be very vast, allowing pharmacists to perform these tasks on all patients

¹¹⁵ See, e.g., Wash. State Dep't Health, Who Can Prescribe and Administer Prescriptions in Washington State,

https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/Pharmacy/WhoCanPrescribeandAdministerPrescriptions (last visited Apr. 29, 2022).

Scope of Practice and Medicaid

23

¹¹¹ Phillip Zhang & Preeti Patel, *Practitioners and Prescriptive Authority*, STATPEARLS (Sep. 27, 2021), https://www.ncbi.nlm.nih.gov/books/NBK574557/.

¹¹² Ajay Kumar, *Ideal Drug Prescription Writing*, 8 World J. Pharmacy & Pharm. Scis. 634, 635 (2019), https://www.academia.edu/38596478/IDEAL_DRUG_PRESCRIPTION_WRITING.

¹¹³ *Id.* at 636.

¹¹⁴ *Id.*

¹¹⁶ Kumar, *supra* note 112, at 635.

¹¹⁷ Alex J. Adams & Krystalyn K. Weaver, *The Continuum of Pharmacist Prescriptive Authority*, Annals Pharmacotherapy (June 15, 2016).

¹¹⁸ *Id.*

within a specific population, or limited to a specific patient.¹¹⁹ Autonomous prescribing happens through the use of a statewide protocol, standing order, or other standards governing independent prescribing; it can be used for a limited range of medications for which a specific diagnosis is not needed.¹²⁰ Autonomous prescribing happens on a spectrum, with standing orders and statewide protocols being more limited, and independent prescribing providing the broadest prescriptive authority.

Standing orders enable assessment and drug dispensing without the need for clinician examination or direct order from the attending provider at the time of the interaction. Under a standing order, certain authorities (sometimes a government official like the state Secretary of Health, sometimes authorized prescribers in local clinics or pharmacies) can write "standing orders" that act like a prescription for everyone in a given population; it could be as broad as everyone in the state, or limited to students at a specific campus or patients in a certain hospital. Standing orders are similar to population-based CPAs, but do not require direct partnership with an attending provider. Standing orders also provide treatment guidelines.

A statewide protocol provides a standard procedure for determining if a drug is necessary and details how to dispense it safely. Statewide protocols are generally used for patient care needs that do not require a new diagnosis or for which a documented diagnosis is known or readily available. The state body authorized to issue statewide protocols varies state to state, and it may be authorized by just one body, like the state health department, or may need to be approved by several bodies, such as the medical board, board of nursing, or board of pharmacy. Like a standing order, the statewide protocol provides treatment guidelines and does not require direct partnership with an attending provider. By definition the protocol applies statewide, unlike standing orders which may be more limited in population application. A statewide protocol and a statewide standing order are essentially the same thing, except that a statewide protocol is generally codified into state law through statute and/or regulation, making it less susceptible than a standing order to future administrative changes. 124

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ Statewide Protocol Workgroup, Nat'l All. State Pharmacy Ass'ns, *Pharmacist Statewide Protocols: Key Elements for Legislative and Regulatory Authority* 1 (Mar. 2017), https://naspa.us/wp-content/uploads/2017/03/Pharmacist-Statewide-Protocols-Key-Elements-for-Legislative-and-Regulatory-Authority.pdf.

¹²² *Id.*

¹²³ *Id.* at 4.

¹²⁴ Allison Orris et al., *Implementing Pharmacist Contraceptive Prescribing: A Playbook for States and Stakeholders*, MANATT (Jan. 2021),

Finally, independent prescribing is the most liberal model of autonomous prescribing; it allows a pharmacist to use their clinical judgment to prescribe medications within specific categories or classes. 125 Idaho currently allows more expansive independent prescribing than any other state. In 2017, pharmacists were granted prescriptive authority for: all OTC medications; medications to treat minor ailments such as flu, strep throat, uncomplicated UTIs, lice, cold sores; medications to prevent motion sickness, Lyme disease; travel medications; immunizations; fluoride supplements; medications to address gaps in care, such as statins for patients with diabetes; tobacco cessation medications; tuberculin skin tests; opioid antagonists; inhaler spacers, nebulizers, diabetes testing supplies, pen needles, syringes; and emergency medications for anaphylaxis like epinephrine autoinjectors and short-acting betaagonist bronchodilators. 126 Two years later in 2019, the State removed the statutory requirement that the board of pharmacy expressly authorize each drug that an Idaho pharmacist can prescribe; the remaining restriction on pharmacist prescribing is that it is limited to drugs for conditions that do not require a new diagnosis or are minor and generally self-limiting. 127 Vermont also enacted expansive independent prescribing authority for pharmacists in 2020. 128 The benefit of this approach is that it avoids the legislature having to add or adjust eligible medications on a recurring basis.

B. Enrolling as a Medicaid Provider

Scope of practice rules govern what a provider can legally do in the state, but do not equate with what Medicaid will pay for. Even with prescriptive authority, APPs must be authorized under a state plan to deliver delineated services and enrolled as a Medicaid provider. No matter if the individual practitioner is not billing directly (*e.g.*, billing is submitted by a rural health center, community health center, or pharmacy), if an individual practitioner is performing the service submitted on the claim, then they must enroll as a Medicaid provider. ¹²⁹

If a service by a particular provider is authorized, providers wishing to provide that service undergo an enrollment and credentialing process to verify qualifications. Typically, the

https://www.manatt.com/Manatt/media/Documents/Articles/Implementing-Pharmacist-Contraceptive-Prescribing v3.pdf.

¹²⁶ Idaho Admin. Code r. 27.01.04.20–.28 (2018).

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¹²⁵ IDAHO CODE § 54-1704.

¹²⁷ 2019 Idaho Sess. Laws 488, (codified at IDAHO CODE § 54-1704.)

¹²⁸ 2020 Vt. Acts & Resolve 178 (codified at VT. STAT. ANN. tit. 26, §§ 2022–2023.)

¹²⁹ 42 C.F.R. § 455.410(b). *See also* Schweitzer & Attala, *supra* note 53, at 412.

individual APP as well as the location where care takes place, like a pharmacy or clinic, must be credentialed. Fee-for-service credentialing, which generally goes through the state Medicaid agency, takes place independently from managed care credentialing, although some MCOs may use a state Medicaid agency data portal to determine whether a provider is qualified. States may consider, or even require, use of a uniform credentialing form, such as the Council for Affordable Quality Healthcare form, which includes standard information about licensure, formal education and training, work history, practice location, and liability insurance. 131

A foundational element of credentialing is the NPI. Organizational providers apply for and receive a Type 2 NPI and can have multiple NPIs, for example to account for individual locations within a chain of pharmacies; individual providers receive a Type 1 NPI and then affiliate with a Type 2 NPI to enroll as a group pharmacist prescriber.¹³²

APPs are often required to maintain training and education competencies, and this curriculum is typically overseen by the relevant state board.¹³³ Maryland, for example, uses a training notification form for pharmacist prescribing of contraception that includes the pharmacist contact information, license number and expiration, and proof of completion of a board-approved training program.¹³⁴ Maryland pharmacists may not prescribe until they have received written confirmation from the board that their training notification form has been accepted.¹³⁵ The Medicaid agency and/or MCOs may also require APPs to submit

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2022).

¹³⁰ In California, for example, some Medi-Cal health plans use the Department of Health Care Services' Ordering, Referring and Prescribing (ORP) list, available through an open data portal, to verify and process claims, https://data.ca.gov/dataset/enrolled-medi-cal-fee-for-service-provider1 (last visited Apr. 29, 2022).

¹³¹ Md. Ins. Admin., Provider Application, https://insurance.maryland.gov/Insurer/Documents/paper-application.pdf (last visited Apr, 29,

¹³² CMS, National Plan & Provider Enumeration System, https://nppes.cms.hhs.gov/webhelp/nppeshelp/MAIN%20PAGE.html (last visited Apr. 29, 2022).

¹³³ See, e.g., Cal. Bus. & Prof. Code § 4052.3; 21 N.C. Admin. Code 36.0807; 22 Tex. Admin. Code § 216.3.

¹³⁴ Md. Bd. Pharmacy, Pharmacist Contraceptive Training Notification Form (June 19, 2019), https://health.maryland.gov/pharmacy/docs/All%20BOP%20Forms/Contraception%20Prescribing/Contraceptive%20Training%20Notification%20Form%2006.19.19.pdf.

¹³⁵ Id.

documentation of the training completion during credentialing.¹³⁶ However, a special certification beyond board-approved training should not be required.¹³⁷

C. Medicaid Claims

Based on what the state agrees to cover in its state plan, the state Medicaid agency produces a fee-for-service provider manual to specify the coding data necessary for payment, as well as a fee schedule. ¹³⁸ In managed care, the Medicaid agency delegates this task to the contracted managed care organization with the expectation that it will pay for all required care, and the agency may remind the MCOs of mandatory policies through bulletins or All-Plan Letters. ¹³⁹ Providers within a managed care network contract with the MCO to define which specific procedure codes they can submit and how much they will be paid for those services.

Payment for medication therapy is particularly complicated by the bifurcation of health insurance claims into medical benefits and pharmacy benefits; drugs and associated care may be covered under the medical benefit, the pharmacy benefit, or potentially both. A drug is typically a medical benefit if it is provider-administered and a pharmacy benefit if it is self-administered, but certain drugs, like injectable contraception, can be administered either way depending on the context.

Because pharmacist services have been historically confined to the pharmacy benefit, the process for submitting a medical benefit claim is less understood by pharmacists; however, it is important to understand the claims process for both types of benefits as pharmacists

¹³⁶ See, e.g., Md. Dep't Health, Pharmacist Prescribers,

https://health.maryland.gov/mmcp/Pages/pharmacist_prescribers.aspx (last visited Apr. 29, 2022); Md. Dep't Health, Pharmacist Prescribers: Checklist for New Applications (Feb. 5, 2020), https://health.maryland.gov/mmcp/SiteAssets/pages/Provider-

<u>Information/ePREP%20Checklist%20for%20Pharmacist%20Prescribers%202.5.20.pdf.</u>

¹³⁷ Sally Rafie, *Five Pearls from the States Forum on Pharmacist Birth Control Services*, Pharmacy Times (July 10, 2019), https://www.pharmacytimes.com/view/5-pearls-from-the-states-forum-on-pharmacist-birth-control-services.

¹³⁸ 42 C.F.R. § 431.18. *See, e.g.*, Wash. State Health Care Auth., Family Planning Billing Guide (Jan. 1, 2021), https://www.hca.wa.gov/assets/billers-and-providers/Family-Planning-bg-20210101.pdf; S.C. Dept' Health & Hum. Servs., Fee Schedules, https://www.scdhhs.gov/resource/fee-schedules (last visited Apr. 29, 2022).

¹³⁹ See, e.g., Cal. Dep't Health Care Servs., All Plan Letter 18-019 at 2 (Nov. 21, 2018), https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2018/APL 18-019.pdf.

expand their scope of practice. 140 To process pharmacy benefit claims, a pharmacist and pharmacy must contract with a third-party pharmacy benefit manager (PBM), use the National Council for Prescription Drug Programs claim standard, and use a unique National Drug Code (NDC) to determine price. 141 For medical benefit claims, a pharmacist and pharmacy must contract directly with the state Medicaid agency or MCOs, complete the CMS 1500 claim form, and use CPT codes from the Healthcare Common Procedure Coding System to determine reimbursement.142

D. Procedural Terminology

Providers have their own language separate from legal authority, and that is procedural terminology; each clinical term is associated with specific tasks that translate into CPT codes and provider payment. Every reported CPT code must also have an associated diagnosis code, demonstrated in the International Statistical Classification of Diseases and Health Problems (ICD-10). When it comes to paying for medication therapy, certain tasks are universally at issue: patient assessment, the prescription drug, a dispensing fee, and potentially drug administration.

Patient Assessment & Counseling. A provider must have enough knowledge of the individual's medical circumstances in order to recommend drug therapy. A provider will need to screen and counsel patients as appropriate in conjunction with issuing a prescription. Counseling in this context goes beyond the counseling associated with dispensing a medication, but entails the evaluation necessary in order to gather information relevant to initiating or continuing prescription medication. 143 Because this care currently falls under the medical benefit, not the pharmacy benefit, states have had to specifically allow for this APP payment. 144

https://www.jmcp.org/doi/pdf/10.18553/jmcp.2008.14.S4-A.7.

¹⁴⁰ Robert C. McDonald, *Managing the Intersection of Medical and Pharmacy Benefits*, 14 J. MANAGED CARE PHARM. S7, S7-S9 (2008),

¹⁴¹ *Id.* at S9.

¹⁴² *Id.* There are also private service platforms that manage enrollment and claims, but they require a percentage of all successful claims as well as large upfront cost, potentially thousands of dollars; providers will need to analyze whether the fees to use these platforms are financially justified by their service volume.

¹⁴³ West Virginia protocol, for example, requires that the pharmacist shall counsel the patient about seeking preventive care, including routine well-woman visits, STI testing, and pap smears.

¹⁴⁴ See, e.g., Cal. Welf. & Inst. Code § 14132.968(β)(1); Md. Code Ann., Health Gen. § 15-148(c); D.C. CODE § 3-1202.08(g-1)(3); MASS. GEN. LAWS ch. 118E, § 10K. Because of the

- Prescription Drug/Device. Prescribing is the actual selection of a specific dose and drug, and must come from a licensed professional with valid prescriptive authority. Prescription drugs are most commonly covered under the pharmacy benefit. However, if a prescription drug is provider-administered, where the provider buys the medications in advance and then bills third party payers after they provide care, it is likely part of the medical benefit.
- **Dispensing.** A dispensing fee pays for a pharmacy to acquire and fill medication, answer routine patient questions, and process insurance and payment. Dispensing fees are covered through the pharmacy benefit, making them an easy lever to modify in incentivizing pharmacist care. While states may consider a temporary increased dispensing fee as pharmacists transition to submitting medical claims, an increased dispensing fee is not a substitute for patient assessment and counseling payment.¹⁴⁵
- Administration. This is the direct application of a drug or device to the body of a
 patient by injection, inhalation, ingestion, or other means.¹⁴⁶ Drug administration is
 most commonly covered as a medical benefit, yet for vaccines in particular,
 administration is often also a pharmacy benefit. Additional drug administrations, such as
 injectable contraception or PrEP, could similarly be included as pharmacy benefits.

technological hurdles that community pharmacies face with medical billing, states may also consider the feasibility of adding patient assessment and counseling to the pharmacy benefit in order to increase uptake of pharmacy-based services.

¹⁴⁵ Illinois, for example, provides a \$35 dispensing fee add-on for 340B purchased contraceptives. Ill. Dep't Healthcare & Fam. Servs., *Important Family Planning Policy Change and Payment Increases* (Oct. 10, 2014),

https://www2.illinois.gov/hfs/MedicalProviders/notices/Pages/prn141010a.aspx. A state could similarly create a dispensing fee add-on for pharmacist-prescribed contraceptives.

¹⁴⁶ See, e.g., Cal. Bus. & Prof. Code § 4016.

COVID-19 Vaccine Administration

The federal PREP Act allows pharmacists to administer the COVID-19 vaccine for the duration of the public health emergency. 147 CMS releases SPA templates for states, particularly whenever new benefit options are added by Congress, and recently released one for COVID-19 vaccine administration. 148 The template contains one section on coverage, and one section on reimbursement; the reimbursement section allows states to establish variable rate schedules and payment methodologies based on provider type. 149 States could use the new template as an opportunity to ensure APP administration is retroactively accounted for in the benefit design, and that COVID-19 vaccine administration is included as both a medical and pharmacy benefit.

V. State Flexibility

While each state takes its own unique approach to licensure authority, there are two primary policy levers that impact access to medication therapy: prescriptive authority and provider payment. Ideally a state would use both levers, because they work in concert to place APPs in a position to use their expanded authority; nonetheless, many state laws address prescriptive authority only. Without guidance or directives on reimbursement, states may struggle to implement expanded prescriptive authority.¹⁵⁰

A. Prescriptive Authority

Scope of practice for health professionals are either authorized through legislation or implemented by state departments of health, professional boards, or another governing state. ¹⁵¹

Scope of Practice and Medicaid

¹⁴⁷ 42 U.S.C. § 247d-6d; HHS, Off. Assistant Sec'y for Health, *Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity Under the PREP Act* 1–3 (Sept. 3, 2020), https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf.

¹⁴⁸ CMS, Medicaid SPA Processing Tools for States, https://www.medicaid.gov/resources-for-states/spa-and-1915-waiver-processing/medicaid-spa-processing-tools-for-states/index.html (last visited Apr. 26, 2022).

¹⁴⁹ *Id.*

¹⁵⁰ See Anu Manchikanti Gomez, Availability of Pharmacist-Prescribed Contraception in California, 2017, JAMA (Dec. 12, 2017), https://jamanetwork.com/journals/jama/fullarticle/2665763.

¹⁵¹ CMCS, State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice Using Collaborative Practice Agreements, Standing Orders or Other

| Advanced Practice Provider Type | Policy Surveillance Research |
|--|--|
| Physician Assistants | Prescriptive authority |
| Nurse Practitioners | Prescriptive authority |
| Optometrists | Prescription of controlled substances |
| Pharmacists | Scope of practice |
| | Prescription adaptation |
| | Self-administered hormonal contraception |
| | <u>Tobacco cessation</u> |
| | <u>Naloxone</u> |

Because comprehensive fifty-state surveys do not exist for all health professions, it may be worthwhile to determine individual state prescriptive authority for providers such as certified registered nurse anesthetists, nurse-midwives, dentists, dental assistants or hygienists, naturopaths, and podiatrists.¹⁵²

B. Payment and Coding Strategies

Three Medicaid reimbursement strategies have emerged for compensating certain APPs: 1) parity with physician payment, 2) a percentage of physician payment, or 3) required payment but reimbursement levels left to payer discretion. For each strategy, we have identified state examples.

1. Physician Parity

New Mexico requires Medicaid to reimburse any participating pharmacist for providing a "prescriptive authority service" at the standard contracted rate that any licensed physician receives for the same service. ¹⁵³

In **Connecticut**, some APPs including nurse practitioners, physician assistants, certified nurse-midwives, and pediatric and family nurse practitioners receive payment for provider-administered drugs and supplies at 100 percent of the applicable physician rates, as opposed to the ninety percent they receive for all other APP services.¹⁵⁴

Predetermined Protocols (Jan. 17, 2017), https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf.

<u>Amendments/Downloads/CT/CT-14-012.pdf.</u>

¹⁵² See, e.g., Wash. State Dep't Health, supra note 115.

¹⁵³ N.M. STAT. ANN. § 27-2-12.30 (2020).

¹⁵⁴ CMS, State Plan Amend. Approval, CT-14-012 (Apr. 26, 2017), https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-

Pharmacies participating in **New York and Kentucky** Medicaid are reimbursed a vaccine administration fee at the same rate as physicians.¹⁵⁵

2. Physician Percentage

California law identifies a list of covered pharmacist services that may be provided to a Medi-Cal beneficiary, and sets the rate of reimbursement for covered pharmacist services at eightyfive percent of the fee schedule for equivalent physician services.¹⁵⁶

In **Indiana**, physician assistants can individually enroll with the Medicaid program as service providers, and reimbursement for their services is set at seventy-five percent of the physician fee schedule rate.¹⁵⁷

Ohio takes a hybrid approach to advanced practice registered nurse (APRN) payment. For a covered service in a hospital setting (excluding nurse anesthetist care and assistant-at-surgery services), payment is capped at eighty-five percent of the Medicaid maximum; for a covered service rendered in a non-hospital setting, as much advanced practice care is, payment can be the full Medicaid maximum.¹⁵⁸

3. Payer Discretion

The **West Virginia** insurance code states that benefits may not be denied for any health care service performed by a licensed pharmacist if the service was within the lawful scope of the pharmacist's license, the plan would have provided benefits if the service had been performed by another provider, and the pharmacist is in the plan's provider network.¹⁵⁹ Health plans are required to include an adequate number of pharmacists in their provider networks, beyond

¹⁵⁵ CMS, State Plan Amend. Approval, NY-09-63 (Mar. 29, 2010), https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/NY/NY-09-63.pdf; CMS, State Plan Amend. Approval, KY-09-011 (Mar. 8, 2010), https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/KY/KY-09-011.pdf.

¹⁵⁶ CAL. WELF. & INST. CODE § 14132.968; CMS, State Plan Amend. Approval, CA-21-0028 (Sept. 15, 2021), https://www.medicaid.gov/Medicaid/spa/downloads/CA-21-0028.pdf.

¹⁵⁷ CMS, State Plan Amend. Approval, IN-17-0010 (Aug. 11, 2017),

https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/IN/IN-17-010.pdf.

¹⁵⁸ Ohio Admin. Code 5160-4-04(C).

¹⁵⁹ W. Va. CODE ANN. § 33-53-1.

pharmacies participating in the prescription drug benefit network.¹⁶⁰ Notably, this law explicitly exempts Medicaid and CHIP from these requirements, but the policy could be extended to Medicaid and CHIP in a future legislative session.¹⁶¹

Hawaii amended its contraceptive coverage law to define contraceptive services as

physician-delivered, physician-supervised, <u>physician assistant-delivered</u>, <u>advanced practice registered nurse-delivered</u>, <u>nurse-delivered</u>, <u>or pharmacist-delivered</u> medical services intended to promote the effective use of contraceptive supplies or devices to prevent unwanted pregnancy (emphasis added).¹⁶²

While the legislature has said this law applies to all insurers in the State, including Medicaid managed care programs, it does not dictate specific reimbursement rates. 163

In **Oregon**, medical services that are necessary to prescribe contraception must be covered in all health plans if the services, explicitly including pharmacist consultations, would be covered for other drug benefits.¹⁶⁴ The law provides no guidance on reimbursement methodology; however, the Oregon State University College of Pharmacy developed a training for pharmacists on successful implementation of patient assessment and proper billing for contraception at the behest of the Oregon legislature and the Oregon Health Authority.¹⁶⁵

In addition to the variable payment strategies, two coding strategies have emerged. In one model, each service is recorded using a code specific to the APP; this makes the most sense if APP payment is different from physician payment for the same service. In the second model, APPs use existing physician codes for the services at issue, but potentially enter a modifier to indicate their specific licensure (the payer can also determine licensure type through the NPI); this makes the most sense if payment for these codes is the same no matter the provider type.

Many codes are specific to the amount of time spent on a patient visit. When developing state coding strategies, it may be prudent to examine the average visit times for relevant services.

¹⁶¹ *Id.*

¹⁶⁰ *Id.*

¹⁶² HAW. REV. STAT. §§ 431:10A-116.6(e), 432:1-604.5(e).

¹⁶³ 2016 Haw. Sess. Laws 205, (codified at Haw. Rev. STAT. § 431:10A-116.6).

¹⁶⁴ OR. REV. STAT. § 743A.066(1)(b).

¹⁶⁵ Or. State Univ. Coll. Pharmacy, *Successful Implementation of Patient Assessment and Proper Billing* (Mar. 3, 2020), https://oregon-state-pharmacy-ce.catalog.instructure.com/browse/oregon/courses/patient-assessment-and-proper-billing.

For example, research from Oregon suggests that pharmacists may require approximately fifteen to twenty minutes to complete a visit, in addition to time required to document the visit and dispense the prescription. While Maryland has designated reimbursement codes for pharmacist prescribing of contraception, they only allow for five or ten minute visits; given the Oregon research, this may not be sufficient time to provide quality contraceptive care. When establishing payment policies, states will want to consider a range of codes to account for visit complexity.

C. State Plan Options

As discussed above, many of the clinical services associated with drug therapy, other than dispensing, are reimbursed as medical benefits under the state Medicaid plan. States could slot APP care under a number of medical benefits, both mandatory and optional. In a 2011 State Medicaid Director letter, CMS stated that tobacco cessation counseling for individuals who are not pregnant may be covered under a variety of Medicaid benefit categories, such as physician services, other licensed practitioner services, preventive services, or rehabilitative services. APPs could also be incorporated into FQHC, rural health clinic, home health, EPSDT, tobacco cessation counseling and drug therapy for pregnant women, COVID-19 vaccine and testing, MAT, or laboratory testing medical benefits.

A critical consideration for states when deciding where to include APP medical benefits is the federal medical assistance percentage (FMAP). The FMAP rate, which is calculated using a statutory formula and varies by state and year, determines the federal government's share of most Medicaid costs. ¹⁶⁹ Certain benefits have an enhanced FMAP, making their inclusion low-cost for states:

Scope of Practice and Medicaid

¹⁶⁶ Timothy P. Frost et al., *Time and Motion Study of Pharmacist Prescribing Oral Hormonal Contraceptives in Oregon Community Pharmacies*, 59 J. Am. Pharmacists Ass'n 222 (Feb. 8, 2019), https://pubmed.ncbi.nlm.nih.gov/30745187/.

¹⁶⁷ Md. Dep't Health, *Pharmacist Prescriber FAQ* (Mar. 23, 2021),

https://health.maryland.gov/mmcp/SiteAssets/pages/Provider-

<u>Information/Frequently%20Asked%20Questions%20-</u>

^{%20}Pharmacist%20Prescribers%203.24.21.pdf.

¹⁶⁸ CMS, Dear State Medicaid Director (June 24, 2011) (SMD # 11-007),

https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/smd11-007.pdf.

¹⁶⁹ ALISON MITCHELL, CONG. RSCH. SERV., R43847, MEDICAID'S FEDERAL MEDICAL ASSISTANCE PERCENTAGE (2020), https://sgp.fas.org/crs/misc/R43847.pdf. For the most recent FMAP percentages, see Medicaid and CHIP Payment and Access Comm'n, *MACStats: Medicaid and CHIP Data Book* (Dec. 2021), https://www.macpac.gov/wp-

<u>content/uploads/2018/04/EXHIBIT-6.-Federal-Medical-Assistance-Percentages-and-Enhanced-FMAPs-by-State-FYs-2019%E2%80%932022.pdf.</u>

- **COVID-19 testing** for the otherwise uninsured receives one hundred percent federal reimbursement;¹⁷⁰
- States receive ninety percent federal reimbursement for **family planning** services, supplies, and administration;¹⁷¹
- Medicaid services provided in a **certified community behavioral health clinic**, such as MAT, receive an enhanced FMAP that further reduces the state share by thirty percent;¹⁷²
- States participating in the Money Follows the Person demonstration receive an enhanced federal matching rate, ranging from seventy-five to ninety percent, for home and community based services provided to Medicaid enrollees during their first year in the community after institutionalization;¹⁷³
- States that cover certain clinical **preventive services** with no cost-sharing, specifically U.S. Preventive Services Task Force grade A or B services and adult immunizations recommended by the Advisory Committee on Immunization Practices, receive a one percentage point increase in their FMAP rate for those services. 174 These states also receive a one percentage point increase in their FMAP for smoking cessation services that are mandatory for pregnant women.¹⁷⁵

After deciding where to add APP care to its medical benefits, a state would submit a SPA outlining the scope of the benefits that will be covered, provider qualifications, and reimbursement methodology. 176 Each state plan presents unique considerations, but a number of SPA options are highlighted below.

¹⁷⁰ MITCHELL, *supra* note 169, at 8.

¹⁷¹ 42 C.F.R. § 433.15(b)(2); see also id.

¹⁷² MITCHELL, *supra* note 169, at 2, 10.

¹⁷³ *Id.* The Money Follows the Person (MFP) demonstration helps Medicaid enrollees who have resided in an institution for at least 60 days return to the community. Examples of services that can be paid for through MFP include personal care assistance, home health care, home modifications, adult day care, respite care, and assistive technology. States are required to continue service provision for MFP participants even after the enhanced federal match period. ¹⁷⁴ MITCHELL, supra note 169, at 10.

¹⁷⁵ *Id.*

¹⁷⁶ Schweitzer & Attala, *supra* note 53.

The most common SPA design for adding APP care is through the optional benefit for "medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law."¹⁷⁷ This is often referred to as the "other licensed practitioner" (OLP) benefit. While this benefit is not eligible for enhanced FMAP, it has the advantage of adding all of an APP's care into one place, rather than spreading it throughout relevant service benefits.

But even under this one OLP benefit, states have a variety of tactics for coverage. The most expansive coverage comes when a state covers all services under multiple APP's scope of practice. **Washington**, for example, covers services from licensed pharmacists, naturopaths, physician assistants, nurse practitioners, psychologists, dental hygienists, denturists, opticians, and midwives, so long as the services are within the practitioner's scope of practice and specialty area.¹⁷⁸ **Maryland** covers advanced practice nursing, including nurse anesthetist, nurse midwife, and nurse practitioner services, as well as physician assistant services.¹⁷⁹

Other states add APP care to the OLP benefit by individual provider. **Vermont** covers physician assistant services provided within the scope of licensed practice as defined under State law. ¹⁸⁰ **Missouri** also covers physician assistant services, but specifically prohibits their provision of abortion care. ¹⁸¹

California and Missouri cover all services performed by a licensed pharmacist under the states' prescriptive authority, although the two scope of practice laws look very different. ¹⁸² In **California**, pharmacists can prescribe self-administered hormonal birth control, naloxone, pre-

https://www.medicaid.gov/medicaid/spa/downloads/WA-20-0029.pdf.

https://www.medicaid.gov/Medicaid/spa/downloads/VT-21-0005.pdf

Scope of Practice and Medicaid

¹⁷⁷ 42 U.S.C. § 1396d(a)(6).

¹⁷⁸ CMS, State Plan Amend. Approval, WA-20-0029 (Mar. 16, 2021),

¹⁷⁹ CMS, State Plan Amend. Approval, MD-17-0006 (Sept. 7, 2017),

https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/MD/MD-17-0006.pdf; CMS, State Plan Amend. Approval, MD-15-0008 (Oct. 6, 2015), https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/MD/MD-15-0008.pdf.

¹⁸⁰ CMS, State Plan Amend. Approval, VT-21-0005 (June 11, 2021),

¹⁸¹ CMS, State Plan Amend. Approval, MO-14-0025 (Jan. 27, 2015),

https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/MO/MO-14-25.pdf

¹⁸² CMS, State Plan Amend. Approval, CA-21-0028 (Sept. 15, 2021),

https://www.medicaid.gov/Medicaid/spa/downloads/CA-21-0028.pdf; CMS, State Plan Amend. Approval, MO-20-0022 (Mar. 3, 2021),

https://www.medicaid.gov/medicaid/spa/downloads/MO-20-0022.pdf.

and post-exposure prophylaxis, nicotine replacement products, flu shots, and travel medications. California also recognizes advanced practice pharmacists who, after meeting certain criteria, may perform patient assessments, order and interpret drug therapy-related tests, refer patients to other health care providers, participate in the evaluation and management of disease and health conditions in collaboration with other providers, and initiate, adjust, or discontinue drug therapy under a CPA. Missouri, on the other hand, only allows pharmacists to administer vaccines and dispense PEP under a CPA, dispense naloxone and nicotine replacement therapy under a statewide standing order, and engage in the designing, initiating, implementing, and monitoring of a medication therapeutic plan with a special board-granted certification.

Other states add to the OLP benefit even more narrowly. **Alabama** and **Arizona** allow pharmacists to enroll and be paid through Medicaid, but only for administration of vaccines. North Carolina also allows licensed pharmacists employed by Medicaid-enrolled pharmacies to administer vaccines, but all other pharmacist care must be performed under a CPA. Maryland adds a covered patient assessment by pharmacist prescribers, but only for contraception. 188

A less common, but more targeted, SPA design adds APP care to specific medical benefits. **Kentucky** submitted a SPA to remove language that did not allow for physician assistant

Scope of Practice and Medicaid

¹⁸³ CAL. Bus. & Prof. Code §§ 4052(a)(10), 4052.01.

¹⁸⁴ CAL. BUS. & PROF. CODE §§ 4052.2, 4052.6.

¹⁸⁵ Mo. Rev. Stat. §§ 195.206, 338.010, 338.665, 338.730. See also Mo. Bd. Pharmacy, *Missouri Pharmacy Practice Guide 2020*, https://pharmacy.umkc.edu/docs/practice-guide.pdf. ¹⁸⁶ CMS, State Plan Amend. Approval, AZ-16-003 (July 13, 2016),

https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/AZ/AZ-16-003.pdf; CMS, State Plan Amend. Approval, AL-19-0005 (May 16, 2019), https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/AL/AL-19-0005.pdf.

¹⁸⁷ CMS, State Plan Amend. Approval, NC-17-0016 (Feb. 5, 2018), https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/NC/NC-17-0016.pdf.

¹⁸⁸ CMS, State Plan Amend. Approval, MD-19-0001 (Mar. 5, 2019),

https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/MD/MD-19-0001.pdf. It is unclear whether adding this through the OLP rather than family planning benefit has an impact on receiving the ninety percent match generally available for contraceptive services.

services under the rural health clinic services benefit.¹⁸⁹ **Ohio** covers medical services rendered by a physician assistant, advanced practice registered nurse, or pharmacist in its rural health clinic and FQHC services benefits.¹⁹⁰ **Arizona** includes medically necessary services provided by a licensed naturopath under the EPSDT benefit, and **Washington** includes evaluation and treatment from advanced registered nurse practitioners in EPSDT.¹⁹¹

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) allowed nurse practitioners, clinical nurse specialists, and physician assistants to certify and order home health services, which could include medical equipment and supplies for people with chronic conditions. ¹⁹² As a result, a number of states, including **Ohio, Colorado, Michigan, Missouri,** and **Virginia**, submitted SPAs to explicitly include coverage of that APP care. ¹⁹³ This care may be eligible for enhanced FMAP if part of the Money Follows the Person demonstration.

State policymakers may consider where APPs can be added to additional Medicaid benefits, with attention paid to FMAP incentives. APPs could conceivably be added to the COVID-19 vaccine and testing benefit, allowing easier access to OTC COVID-19 tests. 194 States can also implement the SUPPORT Act provisions by ensuring qualifying APPs can be reimbursed for buprenorphine care under the temporary MAT benefit; it may qualify for enhanced FMAP if provided in a certified behavioral health clinic. Finally, contraception and many family planning

¹⁸⁹ CMS, State Plan Amend. Approval, CT-14-012 (Apr. 26, 2017),

https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/KY/KY-14-003.pdf.

¹⁹⁰ CMS, State Plan Amend. Approval, CT-14-012 (Apr. 26, 2017),

https://www.medicaid.gov/medicaid/spa/downloads/OH-21-0009.pdf

¹⁹¹ CMS, State Plan Amend. Approval, CT-14-012 (Apr. 26, 2017),

https://www.medicaid.gov/media/file/az-20-00101.pdf; CMS, State Plan Amend. Approval, CT-14-012 (Apr. 26, 2017), https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/WA/WA-20-0004_0.pdf

¹⁹² 42 U.S.C. § 1395f(a); 42 C.F.R. § 440.70.

¹⁹³ CMS, State Plan Amend. Approval, OH-21-0029 (Dec. 9, 2021),

https://www.medicaid.gov/Medicaid/spa/downloads/OH-21-0029; CMS, State Plan Amend. Approval, CO-20-0039 (Mar. 16, 2021),

https://www.medicaid.gov/medicaid/spa/downloads/CO-20-0039.pdf; CMS, State Plan Amend. Approval, MI-20-0008 (Dec. 4, 2020), https://www.medicaid.gov/medicaid/spa/downloads/MI-20-0008.pdf; CMS, State Plan Amend. Approval, VA-20-0017 (Oct. 29, 2020),

https://www.medicaid.gov/Medicaid/spa/downloads/VA-20-0017.pdf; CMS, State Plan Amend. Approval, MO-20-0016 (Aug. 3, 2020),

https://www.medicaid.gov/medicaid/spa/downloads/MO-20-0016.pdf.

¹⁹⁴ Coursolle & Taylor, *supra* note 53, at 8.

related services delivered by APPs can be added to the family planning or preventive services benefits. Although the family planning benefit has a much higher enhanced FMAP than preventive services, the ninety percent match is not available for family planning related services, so STI prevention and treatment delivered by APPs may be best included as preventive services. ¹⁹⁵ Adult vaccine administration could also be included under preventive services.

Even without an enhanced FMAP, state policymakers may consider where care and services delivered by APPs should be added to the rehabilitative services, tobacco cessation counseling and drug therapy for pregnant women, or laboratory testing medical benefits, assuming this care is part of APP scope of practice in the state.¹⁹⁶

D. Federal Guidance

In 2017, CMCS released an informational bulletin on expanded scope of pharmacy practice.¹⁹⁷ The bulletin walks through a number of public health challenges that can be addressed through an expanded scope of pharmacy practice, including naloxone for opioid overdose, tobacco cessation treatment for the prevention of lung cancer, flu shots for the prevention of influenza viral infections, and emergency contraception to prevent pregnancy.¹⁹⁸ The bulletin also reiterates the range of prescriptive authorities that states have used, from collaborative to autonomous prescribing and everything in between.¹⁹⁹ While this is useful, specific SPA templates would be most helpful, as prescriptive authority is only half of the puzzle.

Federal guidance could also be valuable around NPIs, which are critical to provider enrollment and credentialing as well as provider payment. In the context of expanded scope of practice, NPI usage varies by prescriptive authority. Under a collaborative practice agreement, it makes logical sense to use the NPI of the prescribing provider, often a physician. Likewise, under autonomous prescribing, it makes logical sense to use the NPI of the independent prescriber. However, CMS expectations for submitting claims under standing orders or statewide protocols are less clear.²⁰⁰ Under a standing order, a physician has authorized the medication, but an

¹⁹⁵ CMCS, *Medicaid Family Planning Services and Supplies FAQ* (Jan. 11, 2017), https://www.medicaid.gov/federal-policy-quidance/downloads/fag11117.pdf.

¹⁹⁶ CMS, SMD # 11-007, *supra* note 168.

¹⁹⁷ CMCS, State Flexibility To Facilitate Timely Access to Drug Therapy, supra note 151.

¹⁹⁸ *Id.* at 2–4.

¹⁹⁹ *Id.* at 2.

²⁰⁰ 42 U.S.C. § 1396a(kk)(7)(B); see also 42 C.F.R. §§ 431.107(b) and 455.44042.

APP assesses patients to determine whether it is appropriate for the individual patient.²⁰¹ Should providers use the NPI of the standing order issuer or of the APP? A statewide protocol is authorized by a state body, but it is not fully autonomous prescribing. Should APPs apply for and use their own NPI number if practicing under a statewide protocol? This clarification is critical to state implementation of expanded scope of practice laws.

VI. Conclusion

When guided by public health research and comprehensive implementation, expanded prescriptive authority has the potential to increase access and promote better health outcomes. However, Medicaid reimbursement for medications prescribed by and related clinical services delivered by APPs are critical to making expanded scope of practice a reality. This issue brief is intended to provide a roadmap for innovation in the Medicaid program that supports health professionals to practice at the top of their license, with the ultimate goal of shifting health care to a person-centered experience, rooted in autonomy.

²⁰¹ Statewide Protocol Workgroup, *Pharmacist Statewide Protocols: Key Elements for Legislative and Regulatory Authority* (Mar. 2017), https://naspa.us/wp-content/uploads/2017/03/Pharmacist-Statewide-Protocols-Key-Elements-for-Legislative-and-Regulatory-Authority.pdf.