2021 Medication Access Report

Legislative & Regulatory Edition

covermymeds

Legislative & Regulatory Edition

Editor's note: While many healthcare rules and policies were enacted in 2020, especially related to COVID-19, this edition of the 2021 Medication Access Report focuses on those patients' ability to access, adhere and afford medications.

Most legislators came into 2020 anticipating telehealth, interoperability, transparency and patient access to be major healthcare policy priorities for the year. Then in March 2020, Congress, Health and Human Services and other allied bodies reprioritized healthcare policies in response to COVID-19.

As healthcare stakeholders continue to serve patients in a variety of locations through multiple platforms, they need structures in place to ensure continuity of care in the newly developed healthcare landscape.

In addition to continuing pandemic management, more shifts in the healthcare policy landscape may come via federal administration changes and shifting balance in Congress. Congress will continue to prioritize policies relative to the COVID-19 pandemic; however, the pandemic has also highlighted the need to address disparities and inequities in healthcare. Congress and the Biden administration will likely focus on policies that close the access to healthcare gap due to social determinants of health and disparities.

The industry can also expect to see focus on drug pricing and transparency, diversification of benefits and interoperability. Specifically, for healthcare information technology, prioritizations include a person-centered, value-based care environment that supports secure health information access and exchange.[1]

In this edition of the 2021 Medication Access Report, we overview policies that affect care team members, patient medication access and healthcare IT processes for creating interoperable technology solutions.

Hear more from those shaping and affected by healthcare policy at go.covermymeds.com/medicationaccessreport

RESEARCH METHODOLOGY

CoverMyMeds conducted surveys of patients, providers and pharmacists over a two-month period during September and October 2020. We surveyed 1,000 patients, 400 providers and 328 pharmacists to achieve a 95 percent confidence interval and achieved a ±5 percent margin of error.

Patient Survey
The patient survey leveraged the network of patientworthy.com to reach patients with diseases who are more likely to take specialty medications. Patients represented the general population, including age, race, insurance type and area of living demographics.

Provider Survey
The provider survey leveraged a portion of the 750,000 CoverMyMeds provider users.

Pharmacist Survey
The pharmacist survey leveraged a panel of pharmacy professionals as well as CoverMyMeds pharmacy users.

Market Research
CoverMyMeds conducted market research and literature review of reputable sources as well as focus group discussions with patients and industry stakeholders.

ADVISORY BOARD

The Medication Access Report is developed in consultation with an advisory board of healthcare experts representing major organizations across the industry — each with unique perspectives, interests and opinions.

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COVID-19 Healthcare IT Legislation Changes

After years of slow progress, telehealth surged ahead in policy status as providers' offices closed in 2020. Policymakers laid the tracks just barely ahead of the train as healthcare found its path forward through a pandemic. Temporarily pushed aside, data liquidity, interoperability and cost transparency issues came barreling around the bend. This was in part due to the spotlight the pandemic shined on health inequity and access. Improved infrastructure and clearer direction around changes made in response to COVID-19 could help continue forward progress in healthcare IT.

"It's critical to create a level playing field so people have a safety net. They can take their next steps in life with … confidence and aren't constantly worried about the bottom falling out."

–Calif. Asm. Adrin Nazarian (D-Van Nuys)

Federal-level legislation addressing interoperability and information blocking can help create nimble technology solutions at the health-system level.

Read more about the patients this impacts at go.covermymeds.com/medicationaccessreport

Telehealth Policy

While office visits dropped by 65 percent in April 2020, telehealth use soared, peaking at a nearly 6,000 percent increase in visits compared to 2019.[2] Though telehealth use dipped from its high, it still maintained a 2,000 percent increase over baseline levels entering 2021.[2] Seventy percent of patients surveyed said they'd participated in a telehealth appointment in 2020.[3] As the demand increased, legal restrictions were lifted to ensure patients could access the care they needed.

Among the first federal measures to come out of Washington, D.C. in March 2020 were waivers for Medicare telehealth restrictions, expanding telehealth coverage to all Medicare beneficiaries. Telehealth had previously only been available for beneficiaries in rural areas.[4] After former President Trump declared a national emergency on March 13, 2020, the Department of Health and Human Services (HHS) waived licensing regulations so physicians participating in federal healthcare programs could treat out-of-state patients via telehealth technology.[5] Many states did the same, with varying timelines and restrictions.[6]

For patients, this meant increased provider availability and use of telehealth platforms, especially for acute treatment. It also improved access to mental health services, critically important during a time of immense change for patients who didn't previously have an established provider for this service. New patients seeking mental health telehealth visits increased by as much as 50 percent during the latter part of 2020.[7]

The Trump administration also waived The Health Insurance Portability and Accountability Act (HIPAA) sanctions and penalties, opening up providers' options for communicating with patients, including their personal phones and platforms such as FaceTime, Zoom and Skype for telehealth appointments.[8]

From April 2020 to July 2020, the Federal Communications Commission granted a total of 14 waivers of COVID-19 telehealth applications, funneling hundreds of millions of dollars to health systems around the country to expand telehealth programs with new equipment, software and network upgrades.[9]

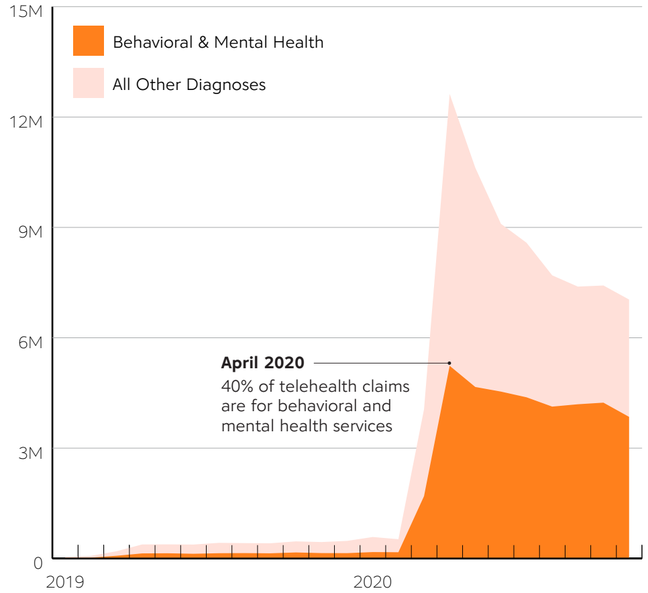
In 2020, over 90 percent of providers offered some kind of telehealth option for patients, while over 50 percent said it was an option for all patients.[10] While 40 percent indicated increases in telehealth services resulted in increased administrative burden, 86 percent noted their overall telehealth experience was positive.[10]

The need and desire for a telehealth option is clear, but there are obvious logistic and regulatory hurdles to overcome if it's to remain an accessible permanent healthcare option.

In April 2020, the Centers for Medicare and Medicaid Services (CMS) expanded availability for physical, speech and behavioral therapists to deliver telehealth services as well as for hospital-based physicians to deliver remote care.[11] Under this same update, CMS increased payments for telehealth visits to match similar office and outpatient visits.[11]

Telehealth Policies Could Significantly Impact Patients Seeking Mental Health Support

While telehealth visits for most clinical classifications spiked after March 2020, mental health disorders were the leading diagnosis for telehealth claims during the COVID-19 pandemic. Relaxed policies and waivers opened up accessibility to remote appointments and diagnoses.



TELEHEALTH Impact Study: Claims Data Analysis, COVID-19 Healthcare Coalition, 2021

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Licensing Waivers and Broader Access

With many new policies in place, the doors to telehealth opened wide, improving patient access to healthcare like never before. But many of these actions are set to expire once the public health emergency ends.

Currently, 41 states have active waivers for licensed providers to practice across state lines, and many set to expire at the end of the public health emergency, with dates varying among states.[13] Some states have also passed parity legislation to ensure telehealth services are reimbursed at the same rate as similar in-person services.[12]

The need and desire for a telehealth option is clear, but there are obvious logistic and regulatory hurdles to overcome if it's to remain an accessible permanent healthcare option for patients.

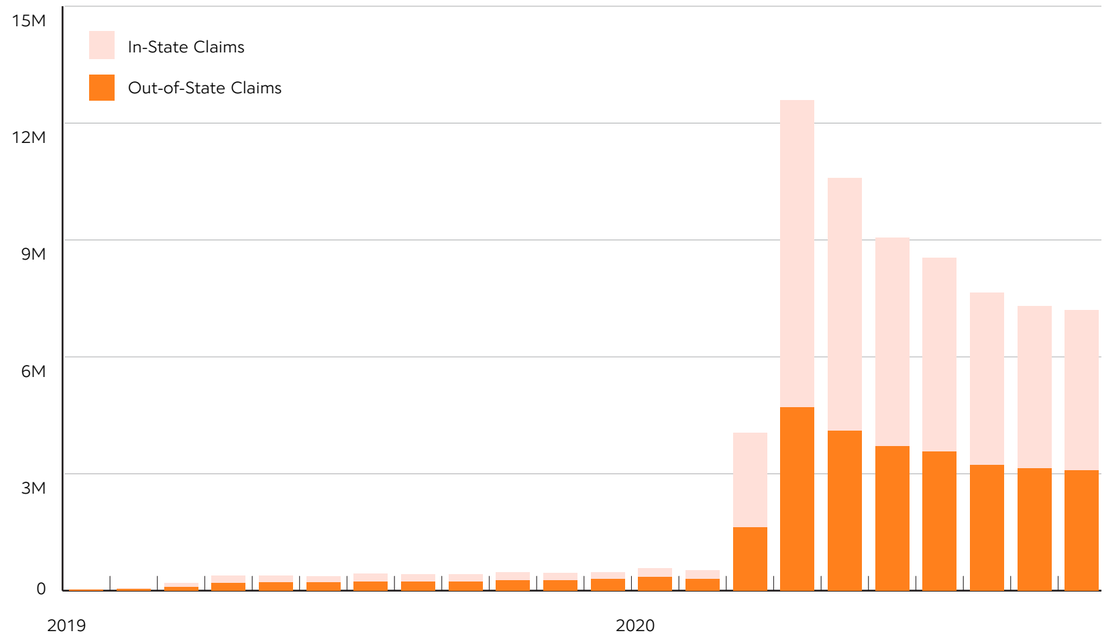
The next question healthcare stakeholders have for legislators is: Will any of these changes become permanent?

While a number of states will look to federal policies to help inform permanent telehealth measures moving out of the pandemic, others have forged their own path. Idaho made telehealth waivers permanent, allowing providers with licenses from other states to work with Idaho patients.[14] Many private insurance plans have taken their own measures to loosen restrictions and improve access.

With patchwork regulations from federal and state governments, health plan and even health system level variable coverage rules, patients face challenges keeping up with what services are covered. Meanwhile, providers will need to track, understand and adapt to regulatory and health plan variations related to telehealth.

Waivers Enabled Out-of-State Provider Appointments During COVID-19 Pandemic

While providers typically need a license from each state in which they practice medicine, waivers allowed licensed providers to practice across state lines. In some areas, this helped fill healthcare workforce gaps for triaging COVID-19 patients via telehealth or providing more options for services via third-party apps.



TELEHEALTH Impact Study: Claims Data Analysis, COVID-19 Healthcare Coalition, 2021.
Data for October-December 2020 are incomplete due to lag time in reporting claims.

Scope of Practice Expansions

COVID-19 prompted the sudden need for providers to test, triage and treat potential coronavirus patients. So, former Secretary of HHS Alex Azar asked states to relax scope of practice policies to increase the healthcare workforce.

Some states, such as Pennsylvania, Tennessee and Wisconsin, relaxed supervision requirements for nurse practitioners and increased their prescribing abilities.[15] Not only did this provide more resources to handle COVID-19, but it also improved provider access for patients at a time when many faced delayed or canceled appointments, closed offices and changes in coverage due to job loss.

Pharmacist roles expanded perhaps even more dramatically. In a recent CoverMyMeds pharmacist survey, more than two-thirds of those surveyed had taken on new responsibilities since COVID-19.[16] In August 2020, pharmacists became federally authorized to order and administer COVID-19 tests.[17] In the same month, following plummeting childhood immunization rates, HHS also authorized pharmacists to administer routine vaccinations to children ages 3 to 18.[18] HHS also expanded scope of practice to allow pharmacy interns and pharmacy technicians to administer vaccines under the supervision of a licensed pharmacist.[19]

Relaxed policies at the state level on pharmacy remote work also widened the path for pharmacist practice. This allowed those in the pharmacy to better serve patients during normal hours of operation. With some patients avoiding or unable to access providers' offices due to COVID-19 precautions, they were more often in front of their pharmacist for health-related questions. More than one in four patients said they've relied more on their pharmacist to provide information regarding their condition and medication due to the pandemic.[3] By routing managerial tasks and phone calls to remote workers, pharmacists were more available to counsel patients on medications or administer vaccines and COVID-19 tests.

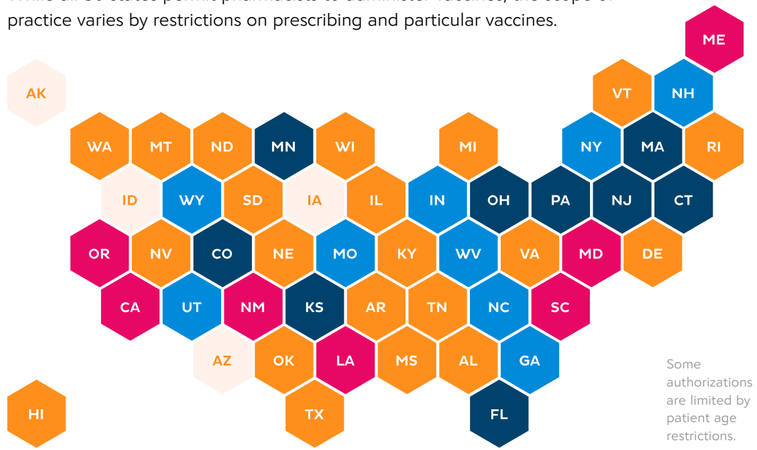
Waivers also allowed pharmacists and technicians with valid licenses to practice across some state lines during the public health emergency. This opened the gates for improved public health response across the country as some pharmacists assisted with mass vaccination efforts in states hit hard by COVID-19.[20] This also opened the gates for improved public health response across the country as some pharmacists were called to assist with mass vaccination efforts in other states.[21]

While pharmacy roles have great potential to alleviate primary care burdens and become a more active part of the patient care team, the conjoined issues of scope of practice and reimbursement prevent them from providing a wider range of services, including prescribing. Most often, affordability and access challenges are handled at the pharmacy, but pharmacists are often left holding the bag, waiting on providers offices to submit prior authorizations (PA) or change to an alternative medication.[10,16]

Currently, 37 states allow pharmacists provider status under Medicare Part B rules, which can complicate the reimbursement process.[22] More than 40 pieces of legislation are currently pending in states regarding pharmacist provider status, ranging from prescriptive authority to COVID-19 medication administration.[22] Most states allow collaborative practice agreements, in which a pharmacist and a physician have an agreement to allow pharmacists certain patient care authority such as adjusting medications, prescribing and ordering labs.[23] By granting pharmacists provider status, they have the potential to improve patient care through expedited PA, medication changes and/or taking and billing for labs, like A1C, in support of value-based arrangements.

Pharmacists Can Administer Vaccines in Every State to Varying Degrees

While all 50 states permit pharmacists to administer vaccines, the scope of practice varies by restrictions on prescribing and particular vaccines.



Some authorizations are limited by patient age restrictions.

In-workflow technology at the pharmacy could further boost time savings and reduce administrative workload for the entire patient care team. Pharmacists using a solution that provided real-time PA status updates saw an average 14 percent increase in paid claims than those using standard electronic PA request submission methods.[24]

- Pharmacists can administer any vaccination if prescribed by another HCP
- Pharmacists can administer any vaccination
- Pharmacists can administer CDC/ACIP-recommended vaccinations
- Pharmacists can administer CDC/ACIP-recommended vaccinations if prescribed by another HCP
- Pharmacists can administer some vaccines

Pharmacist Immunization Authority, National Alliance of State Pharmacy Associations, 2020

Technology to Support Healthcare Anywhere

Telehealth and healthcare consumerism are the present and future of healthcare technology. As a result, providers and pharmacists and their technology partners are answering the call for patient-centered care in a wide variety of settings. More than half of providers surveyed said their office plans to continue telehealth after the COVID-19 pandemic, despite the increase in administrative burden.[10] For improved telehealth experiences, the fewer programs and interfaces with which a healthcare team member needs to interact, the better.

Legislative reform can help open channels for continuity of care, prescription decision support and healthcare access. Regulatory improvements can ensure this data remains mobile. Advancing data liquidity policy can empower patients to securely access and exchange information about their benefit design, their medical and care records through apps, portals and websites and improve choice for better adherence and affordability.

Most federal efforts regarding interoperability and data sharing have focused on EHRs. There is clear recognition that interoperability, inclusive of data liquidity, must span the range of health IT and the care continuum.

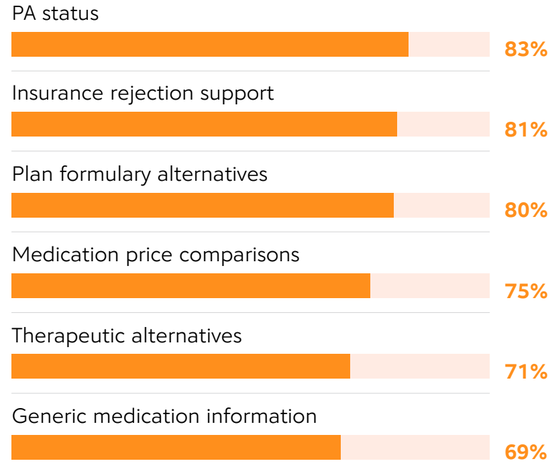
Nimble prescription decision support technologies inclusive of real-time prescription benefit (RTPB) can surface patient cost and benefit details. With greater access to updated formulary and benefit data, these solutions can foster provider-patient discussions on financial decisions before patients head to the pharmacy. This can help reduce sticker shock at the pharmacy — which two-thirds of patients faced last year, leading one third of them to abandon their prescription.[3]

Technology coupled with complete informative data sources can provide a more holistic picture of care and access for the patient and the care team. This data can include medication alternatives, previously tried and failed medications, drug interactions and affordability options. With technology that considers affordability and choice at the point of prescribing, patients and providers have increased options to improve adherence.

At the pharmacy, integrated systems are especially important as remote work grows and real-time status updates become critical. Even though communication to and from providers offices and insurance companies can be routed to remote workers, it's still the most challenging part of the job, and most often done over the phone. Over 82 percent of pharmacists surveyed said it's important they stay in-workflow for daily tasks.[16] When asked about their ideal tool, an overwhelming majority of pharmacists said they'd want PA status and insurance rejection information to be integrated.[16] And with 37 percent of patients unaware of drug manufacturer patient assistance programs, it makes sense that 83 percent of pharmacists said they'd also want patient education materials in a tool.[3,16]

Healthcare innovation is ready to serve patients, providers and pharmacists, but technology is often left waiting in the wings while the legislative stage is slowly set.

Majority of Pharmacists Want PA Status and Insurance Rejection Information in Their Ideal Tool



CoverMyMeds Pharmacist Survey, 2020

Federal Legislation Developments

The Biden administration's top healthcare priority in 2021 will be the COVID-19 public health emergency. But such a far-reaching crisis has the potential to create policies that shape a more accessible, interoperable national healthcare framework moving forward.

Some of these policies are now taking effect. Just before the pandemic swept into 2020, the Office of the National Coordinator (ONC) for Health Information Technology and CMS released twin final rules that set the tone for the future of healthcare access and interoperability.

"The systems we operate within are the biggest (healthcare) barrier. We created these systems. We can change them."

–Joan Werblun, RN, Board Chair, California Chronic Care Coalition

Federal and state legislators moved quickly to address healthcare disparities highlighted by COVID-19. For lasting change, some may need to become permanent.

Read more at go.covermymeds.com/medicationaccessreport

The ONC Final Rule

The ONC 21st Century Cures Act Final Rule, released March 9, 2020, implements the interoperability and information blocking sections of the 21st Century Cures Act, a broader piece of bipartisan healthcare legislation passed in 2016.

The Final Rule is unlike HIPAA, which safeguards protected health information from being shared or received unless authorized. The Final Rule specifically prioritizes electronic health information (EHI) sharing, especially with patients, while maintaining privacy and security. In a recent survey, 81 percent of patients supported enabling different healthcare providers to share patient health record information between their EHR systems.[25] Sixty-one percent said they wanted to download their healthcare records to mobile device apps.[25]

To improve access to healthcare data, the Final Rule addresses those things which stand in the way. Information blocking is the antithesis of interoperability. While industries such as retail and telecommunications lead the way in digital transformation, the healthcare industry lags due to regulations around sharing patient data, including interference with interoperable systems.[26]

The Final Rule prohibits healthcare IT developers, providers (including pharmacists), health information exchanges and health information networks from restricting, unnecessarily complicating or misusing the authorized access, exchange or use of EHI. The rule outlines eight specific exceptions to information blocking, including preventing harm and health IT performance.[27] However, the rule is not inclusive of all information or data holders in the healthcare ecosystem, including health plans or their intermediaries, unless they define themselves as such.

The information blocking piece also designates a common language and data classes for health information exchange, including terms and fields for care team members, patient demographics and clinical notes within EHRs and apps. The data elements found in the United States Core Data for Interoperability (USCDI) also designates standards for relevant data elements, such as Systematized Nomenclature of Medicine — Clinical Terms (SNOMED) for drug class.[28]

Patients Want Access and Sharing Capabilities for Their Health Data

The majority of patients in a recent survey* indicated they want access to their health data, especially when it comes to clinical results and insurance information. Most also want their providers to be able to share their health data with other providers and health systems.

Percentage of Patients Who Would Like Access	Percentage of Patients Who Support Providers' Ability to Share Data	
84%	48%	Insurance billing and claims information
74%	52%	Behavioral or mental health history
88%	71%	History of medical conditions and past diagnoses
87%	70%	Treatment plans
84%	67%	Physician and clinical notes on medical care
89%	74%	Laboratory test results
87%	76%	Vital signs, such as blood pressure
87%	76%	Radiology images and reports
80%	69%	Family medical history
61%	51%	Substance use history
87%	78%	Medications and prescription medicines (current and past)
87%	78%	Immunizations
57%	48%	Information such as exposure to violence or history of physical abuse, hunger or lack of access to healthy food, or homelessness or lack of access to housing
82%	76%	Do not resuscitate orders (DNRs) or end-of-life care preferences
83%	80%	Allergies
58%	63%	Demographic information

*PEW HIT National Survey, The Pew Charitable Trusts, 2020

The ONC Final Rule (cont.)

The ONC 21st Century Cures Act Final Rule established application program interface (API) requirements for healthcare IT developers. APIs provide a set of definitions and protocols for applications to interact.

The Final Rule requires clinical data to be exchanged through Fast Healthcare Interoperability Resources, or FHIR, developed by standards organization H7 International. FHIR provides a formalized way to exchange health information among technologies. This standardization opens up healthcare IT innovation by having APIs speak the same language. FHIR provides standards for both information content and transport.

Open APIs, required through the Final Rule, running on FHIR, will allow hospitals, providers and health systems to not only select the apps and EHRs that best suit them, but also allow easier data exchange among them.

This allows improved continuity of care by removing the information sharing burden from patients, especially those who visit multiple specialists, a primary care provider and specialty pharmacies. It also relieves burden on providers. Of providers with patients on complex therapies, 55 percent said electronic communication to other healthcare parties would exist in their ideal tool.[10]

Providers will also have the freedom to switch EHRs without worrying about losing crucial data such as clinical notes. Technology will likely also be more user friendly with consistently named data fields and familiar interfaces. This can reduce onboarding and training time when introducing new tools and improve the user experience, a contributing factor to provider burnout. Seventy percent of physicians in one study reported stress related to marginal time for documentation, excessive EHR use and dissatisfaction with healthcare IT technology.[29]

Patients, the center of the Final Rule, will be able to request and access their EHI on demand through portals and smartphone apps, no matter their provider, plan or healthcare system. This creates portable patient health data, expanding upon HIPAA to allow data liquidity, except in certain situations.

For healthcare IT, having a standardized data set can help reduce costs and implementation complexity. The Final Rule provisions also protect intellectual property, maintaining a competitive and innovative marketplace.

ONC Final Rule Deadlines

The original implementation dates for the Final Rule were delayed due to COVID-19. Below are the timeframes for compliance.

2021

April 5, 2021

Information Blocking Rules Effective

Developers will be required to be compliant of information blocking rules, communications conditions and maintenance certification and API certification requirement.

Dec. 15, 2021

Real-World Testing

Real-word testing should commence for developers of interoperability technology in appropriate market cases.

2022

April 1-30, 2022

Certification Attestations

Health IT developers must send attestations to ONC to show they've met certification requirements.

Dec. 31, 2022

Standardized Patient API Access

Standardized API access should be available for patients and populations services using the FHIR 4.0.1 standard, among other specifications. Developers must attest if they've implemented new encryption authentication credentials and multi-factor authentication certification criteria and update from 2015 certification criteria for clinical document architecture, electronic prescribing, support security tags, care plan attestation, privacy and security criteria and application access data category requests.

2023

March 15, 2023

Real-World Testing Results

Developers must make real-world testing results from 2021 publicly available.

Dec. 31, 2023

EHI Data Export

Developers must electronically export all EHI that can be stored at the time of its product certification.

CMS Interoperability and Patient Access Final Rule

The CMS Interoperability and Patient Access Final Rule was also released on March 9, 2020. The CMS Final Rule provides CMS-regulated payers with specific guidance for privacy, security and standards related to data exchange, information blocking and patient access to their health data.

Much like the ONC Final Rule, the CMS Final Rule requires implementation of a secure, standards-based patient access API, using HL7 FHIR 4.0.1 that allows patients easy access to their healthcare data through a third-party app of their choice.

The CMS Final Rule will require a provider directory API, payer-to-payer data exchange, increased frequency of federal-state data exchanges, public reporting and information blocking provisions, digital contact information and admission and discharge and transfer event notifications.

CMS Final Rule Deadlines

2021

July 1, 2021

Enforcement of Patient Access API

CMS-regulated payers will be required to implement and maintain an HL7 FHIR 4.0.1 API where patients can easily access claims and appointment details as well as other clinical information through third-party apps.

Enforcement of Provider Directory API

CMS-regulated payers (except those who have already implemented) are required to make provider information available through a standards-based API. This will help patients find the right provider for their condition and open care-coordination possibilities for providers.

2022

Jan. 1, 2022

Payer-to-Payer Data Exchange Implementation

CMS-regulated payers will be required to provide clinical data, as specified under USCDI standards, to patients when requested. This would allow patients more freedom to move among payers over time and also allows for improved continuum of care throughout the patient journey and over a patient's lifetime of providers and payers.

April 1, 2022

Increasing Frequency of Federal and State Data Exchanges

States must send enrollee data for individuals eligible for both Medicare and Medicaid to CMS daily, instead of monthly. This improves the patient experience, ensuring services are billed correctly the first time and reduces provider administrative burden.

ONC Federal HIT Strategic Plan

In January, ONC released their draft 2020-2025 Federal HIT Strategic Plan, which outlines federal health IT (HIT) goals and objectives, focusing on individuals' access to their EHI. The plan was developed in collaboration with over 25 federal organizations, received nearly 100 public comments, and was finalized in November 2020. The Plan will serve as a five year framework in which ONC will prioritize and tackle issues related to healthcare cost, access and burden challenges through interoperability in the healthcare ecosystem, enabling secure data exchange.[1]

CMS ePrescribing Standards Update

In 2019, CMS issued a proposed rule to update PA processes for Medicare Part D, the prescription drug coverage component for Medicare beneficiaries. Under this proposed rule, all Medicare Part D plans would be required to support electronic PA (ePA) transaction standards developed by the National Council for Prescription Drug Programs (NCPDP). CMS issued the final rule (CMS 4189-F) December 2020. Part D plans are required to accept ePA transactions starting January 2021, but due to a federal regulatory freeze, the effective date was moved to March 30, 2021 to allow department officials opportunity to review and consider this and other new regulations.

Contract Year 2021 and 2022 Medicare Advantage and Part D Final Rule

Several changes included in this rule for Medicare Advantage and the Medicare Part D program intend to provide senior patients with improved healthcare consumerism and drug choice. Among these are the requirement for Part D plan sponsors to implement a beneficiary real-time benefit tool that would allow enrollees to view accurate, timely and clinically appropriate patient-specific real-time formulary and benefit (RTFB) information. Plans can use existing patient portals, develop new portals or use a computer application to fulfill this requirement. Plans will also provide RTFB information to enrollees who call the plans' customer service center. This requirement goes into effect for relevant plans Jan. 1, 2023.

State Legislation Developments

Much like their federal counterparts, state legislative and regulatory bodies will continue to hold COVID-19-related issues as a top priority moving into 2021 while also addressing budget deficits and healthcare access concerns.

For many states, restrictions on the number of proposals heard in limited session days and committee meetings made for somewhat slow progress in 2020. This is also likely in 2021 sessions.

"I believe transparency is the biggest problem with healthcare."

–Julie Griffin,
Vice President of
Government Affairs,
Tennessee Medical
Association

Julie paid cash for her prescription after surgery when she learned her insurance wouldn't cover it. But not all patients can do so, and she's working to change that.

Read more at go.covermymeds.com/medicationaccessreport

Copy Accumulator Adjustment Programs

Back on the legislative docket this year for many states are copay accumulator adjustment programs (CAAPs). Starting in 2018, many payers and pharmacy benefit managers (PBMs) put CAAPs in place to prevent the value of a manufacturer copay card from being used toward a patient's deductible or out-of-pocket maximum.[30] These copay cards, or coupons, provide patients payment assistance on their out-of-pocket drug costs, often up to a certain amount per year.

For patients on high deductible plans, accounting for nearly half of those under 65 on employee plans and 90 percent of those insured through the ACA marketplace, CAAPs could lead to prescription abandonment.[31,32] If a patient under a CAAP chooses to forgo insurance to use a copay card, they risk exposure to the full cost of the medication later in the year, as many copay cards have a maximum amount or use limit. During the copay card use period, their prescription costs would not be applied to their deductible, leading to additional out-of-pocket expenses. In a 2018 study, the average copay card value per claim was $229.[33] At this cost, nearly 50 percent of patients are likely to abandon these prescriptions.[34]

In July 2020, the HHS Notice of Benefit and Payment Parameters for 2021 went into effect. These parameters established that financial support from a drug manufacturer could be used toward deductibles and out-of-pocket maxes, but plans could exclude it, even in cases where drugs had no available or medically appropriate equivalent.[35]

States are now on the hook to regulate CAAPs. Arizona, Illinois, Virginia, West Virginia and Georgia have passed laws restricting CAAPs to varying degrees. There are currently 18 states with proposals to restrict accumulators.[36]

More states are likely to address the ability for manufacturer coupons, as well as other payments made outside of the benefit design, to be applied to patient's deductible and out-of-pocket max. To further improve patient price transparency, point-of-prescribing technology should include manufacturer discounts. Since many CAAPs are still relatively new to the market, healthcare solutions that provide these benefit details in states that don't ban CAAPs can help patients prepare for out-of-pocket costs. By making a financial game plan with their provider, patients can avoid sticker shock at the pharmacy throughout the year.

Patients Pay More Out of Pocket with Copay Accumulator Programs

With a CAAP in place, drug manufacturer coupon cards don't count toward a patient's deductible or out-of-pocket maximum. This means, barring other medical costs, patients are responsible for higher costs and for a longer period of time than with plans without CAAPs.

The following are example scenarios of a plan with and without a copay accumulator program in place:

Patient deductible: $4,400
Annual out-of-pocket maximum: $7,900
Monthly prescription cost: $1,675
Manufacturer copay assistance: $7,200
Cost-sharing for specialty tier prescription: 50% coinsurance, after the deductible is met

Plan Deductible Met
Copay Assistance Limit Met
Annual Out-of-Pocket Maximum Met

Plan Without a Copay Accumulator Program

	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	Total	
Consumer Pays	$0	$0	$0	$0	$0	$0	$550	$150	$0	$0	$0	$0	$700	**Insurer Collects** $7900
Copay Assistance	$1,675	$1,675	$1,050	$837.50	$837.50	$237.50	$0	$0	$0	$0	$0	$0	$7,200	
Remaining Deductible	$2,725	$1,050	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0		

Plan With a Copay Accumulator Program

	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	Total	
Consumer Pays	$0	$0	$0	$0	$1,175	$1,675	$1,550	$837.50	$837.50	$837.50	$837.50	$150	$7,900	**Insurer Collects** $15,100
Copay Assistance	$1,675	$1,675	$1,675	$837.50	$500	$0	$0	$0	$0	$0	$0	$0	$7,200	
Remaining Deductible	$4,400	$4,400	$4,400	$4,400	$3,225	$1,550	$0	$0	$0	$0	$0	$0		

Copay Accumulator Adjustment Programs, The AIDS Institute, 2018

Pharmacy Anti-Gag Clause Legislation

Expanding price transparency for patients extends to the pharmacy as well, where pharmacists are sometimes prohibited from telling patients about cost-saving measures. These "gag clauses" prevent pharmacists from providing information on lower-cost drug alternatives, generics or a lower cash price outside of insurance. Pharmacists who do not comply risk penalties that could impact their business.

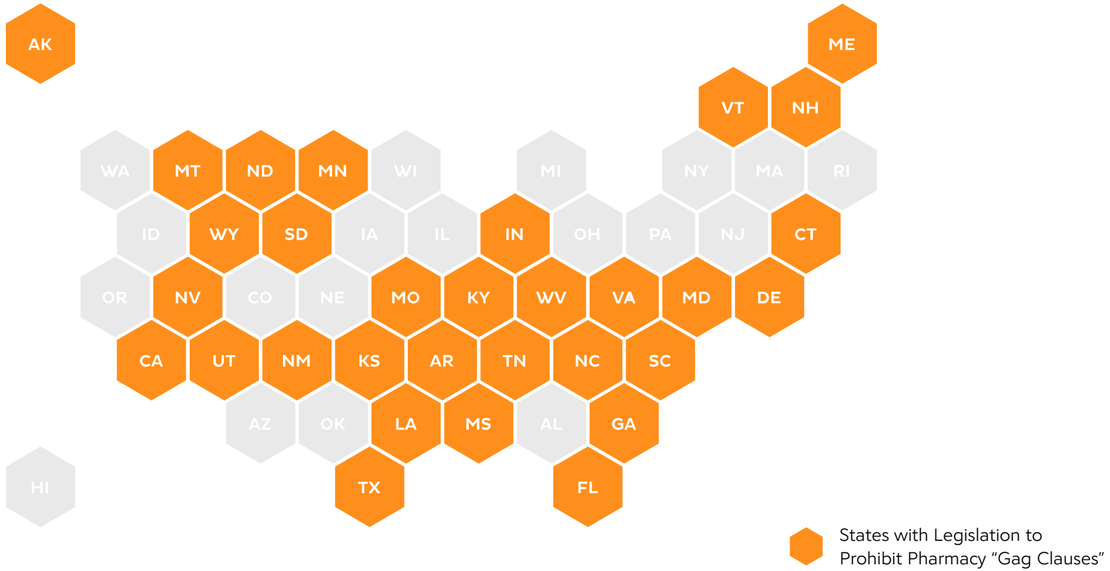
The 2018 Know the Lowest Price Act banned Medicare gag clauses for Medicare beneficiaries and the Patient Right to Know Drug Prices Act, passed the same year, applies to commercial plans. These acts prohibit payers and PBMs from restricting a pharmacist's ability to provide drug pricing information when there's a discrepancy between a drug's cost under a plan and a drug's cost when purchased without insurance.

Many states have drawn their own line in the sand in regard to gag clauses, with 33 states enacting laws preventing them, with policy varying by state. For other states, this policy movement is back on the table in 2021. In Massachusetts, for example, the Senate approved a bill that would require pharmacists to notify patients of the lowest price on their medication — whether through insurance or not.[37]

While drug pricing transparency legislation keeps patients at the center, the ability to have affordability conversations with patients helps elevate the pharmacist as a member of the care team. To truly step into this role, pharmacists need tools to help alleviate manual processes and surface the best price within workflow. Both pharmacists and providers surveyed said patient affordability issues are most often addressed at the pharmacy.[10,16] Three-fourths of pharmacists surveyed said their ideal tool would include medication price comparisons and nearly half said they have to go outside their pharmacy system to complete daily tasks.[16]

Pharmacists are Limited by 'Gag Clauses' in Some States

Under pharmacy "gag clauses," some plans prevent pharmacists from giving patients information on lower-priced drug alternatives. Currently, 33 states have laws preventing this.



National Conference of State Legislatures, 2019

Patient Choice and Transparency Legislation

Multiple states are also introducing legislation this year to address price transparency and coverage information at the point of prescribing. These bills have the potential to reduce provider burden, simplify the PA process and improve patient adherence by enforcing cost and coverage information at the point of prescribing, before patients reach the pharmacy counter.

RTPB tools used to surface real-time prescription pricing can be extremely helpful for patients in sparking affordability conversations with providers. While many providers have access to formulary and benefit information within their EHR, 79 percent in one survey said they seldom trust this information.[38] Over three-fourths of providers reported patient out-of-pocket costs are rarely or never available within their EHRs.[38]

Limited patient-specific, real-time data from payers and PBMs could lead to lower provider adoption or use of RTPB tools. Without out-of-pocket cost information, patients risk sticker shock at the pharmacy, and a recent patient survey shows when prescriptions cost more than expected, over a third of patients leave without it.[3]

In one study, when providers used a prescription decision support solution like RTPB, patients were 19 percent more adherent to picking up their medication.[24]

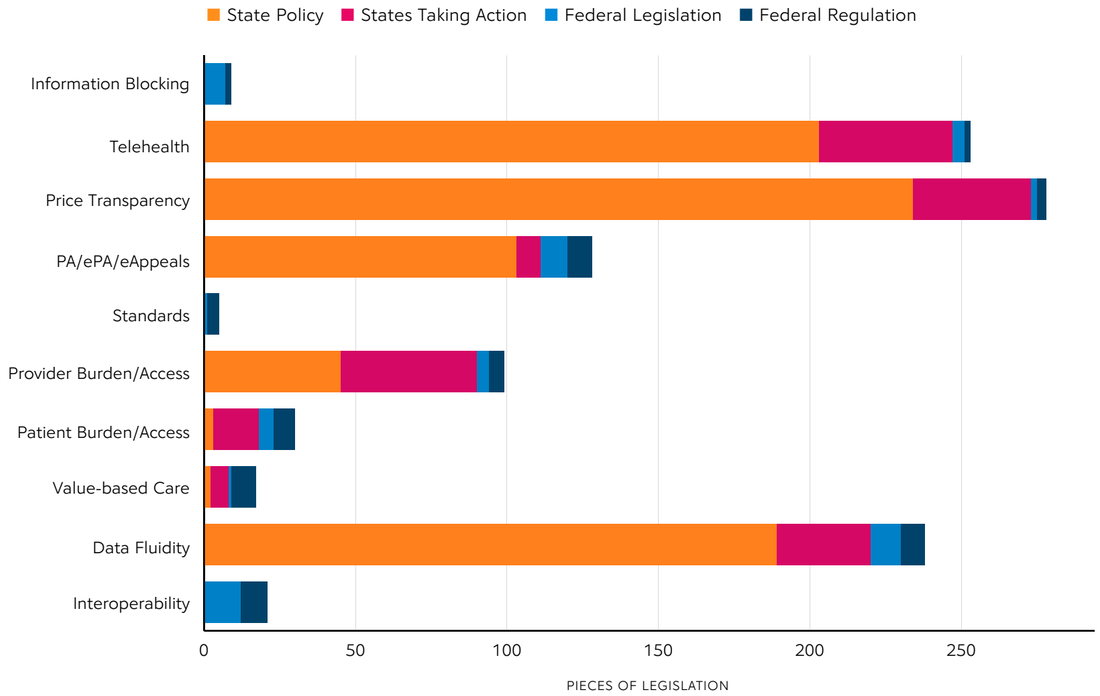
PRESCRIPTION PRICE TRANSPARENCY IN THE STATES

In California, the Patient Choice and Transparency Act (AB 752) would require patient eligibility information, including benefits verification, to be available for prescribers in real-time and delivered in industry-accepted standards. Similar active bill proposals have been drafted in Massachusetts (HD2942/SD1493), New York (A5411/S4620) and Tennessee (H1530/S1249), and others are anticipated in Colorado, Ohio, and Pennsylvania. In Virginia, lawmakers will convene a study over the summer and report back to the legislature in the next session.

This legislation would also open pathways for more patient-facing tools that offer improved patient choice and access both in the provider's office and remotely. Combined with federal measures aimed at open access and improved interoperability, the stage is set for the coming age of healthcare consumerism and patient empowerment.

2021 State Legislature Priorities: Telehealth, Price Transparency and Data Fluidity Dominate

While federal policy will set the stage for much of the general health IT interoperability standards and regulations, it will be up to the states to rule on many patient-centered topics such as telehealth and price transparency. These topics will address payers and PBMs, especially private and commercial plans, and bring point-of-prescribing data transparency to the forefront in 2021.



CoverMyMeds internal data, 2021

Electronic Prior Authorization State Legislation

Continued advocacy of ePA at the federal and state levels highlights the industry's commitment to modernizing healthcare and protecting patients. Many states continue to adopt PA and ePA legislation, with laws ranging from use of a standardized form for submission to mandating the use of ePA and specifically naming the NCPDP SCRIPT Standard.

Recent and Proposed ePA Legislation by State

ARIZONA
HB2621

This measure amends Arizona code to create uniform prior authorization forms for covered health care services directly for the department but also will affect payers and providers. These forms must be approved by Jan. 1, 2022. Providers and utilization review agents must begin exclusively using these forms by Jan. 1, 2023.

FLORIDA
HB1001

A health insurer must authorize or deny a protocol exemption request or respond to an appeal of the health insurer's granting or denial of a request within: 72 hours after receiving a completed PA form for nonurgent care situations or 24 hours after receiving a completed PA form for urgent care situations. If enacted, this measure takes effect July 1, 2021.

GEORGIA
SB195

This measure requires the Commissioner of Insurance to create rules and regulations to prescribe a single, standard form for requesting PA or prescription drug benefits that may not exceed two pages. It also requires an insurer and PBM to accept the PA form for any prescription drug as required by a health benefit plan and deem a fully populated standard prescription drug PA form as a complete PA request.

MAINE
LD2106

Requires the health insurer's electronic transmission system to comply with the process of accepting and responding to PA requests in real time. This must be facilitated by a carrier with other carriers, PBMs, health systems, providers, pharmacies and other third parties, including, but not limited to, intermediaries, real-time networks, switches and translation services.

MARYLAND
MD Code Ann. 19- 108.2

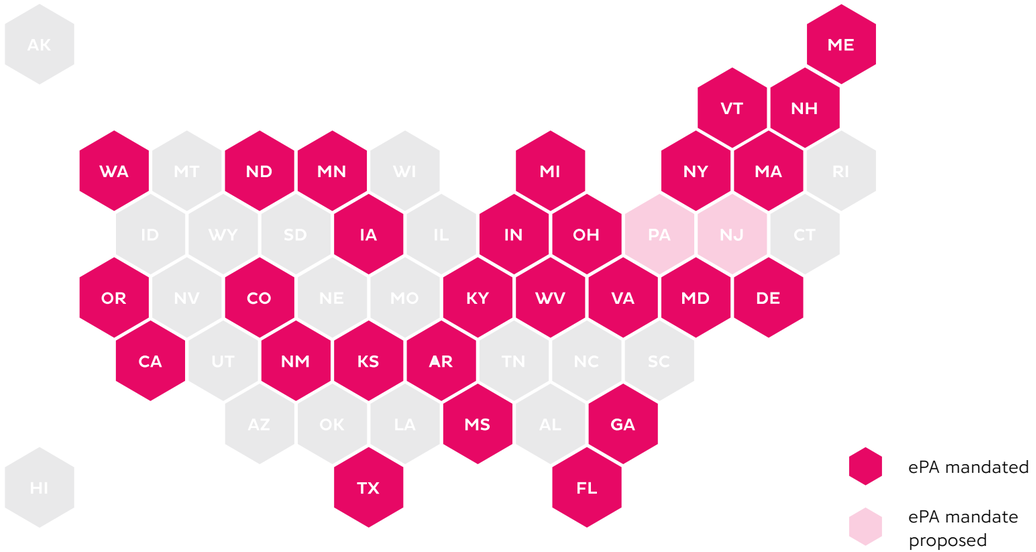
Online, web-based processes are required by payers and PBMs. Providers are required to use payer web portal OR standard transaction that has been established and adopted by the healthcare industry via EMR.

NEW JERSEY
NJ 1850

The bill provides that no later than Jan. 1, 2021, a carrier shall accept and respond to a PA request for medication coverage, under the pharmacy benefit part of a health benefits plan, made through a secure electronic transmission using the NCPDP SCRIPT Standard electronic PA transactions. Facsimile, propriety payer portals and electronic forms shall not be considered secure electronic transmission.

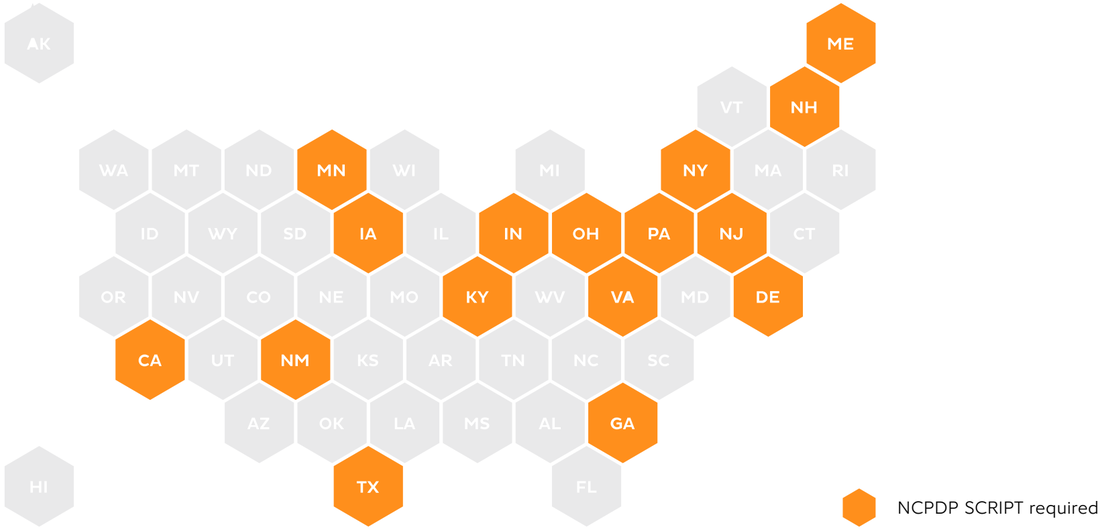
States Currently Mandating PA Requests be Submitted Electronically

The states below mandate or propose mandating all PA requests to be submitted electronically. Though ePA legislation can move the industry forward by advocating, or even mandating, widespread use of efficient tools, it's important new legislation aligns with the most cutting-edge ePA technologies and standards to truly streamline the PA process.



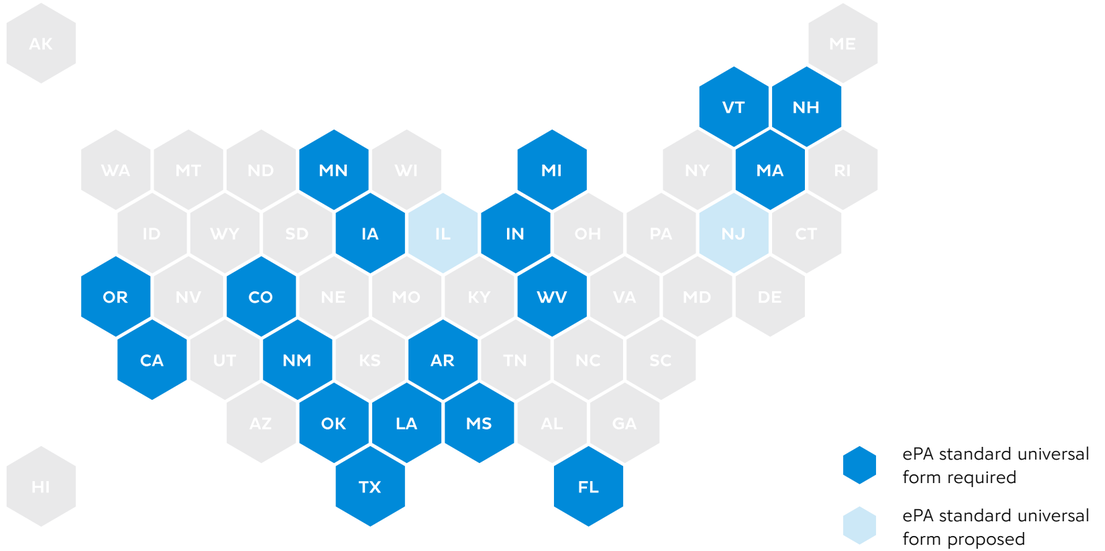
States Currently Designating NCPDP SCRIPT as the ePA Standard

The states below require the use of an electronic method for submitting PA requests specifically in compliance with the NCPDP SCRIPT Standard. For the future of healthcare, it's critical that state legislators consider pre-existing ePA solutions in their states and adopt standard-form, ePA-specific legislation. Different ePA forms and standards among states may significantly challenge stakeholders operating in multiple states. The NCPDP SCRIPT for ePA transactions uses a specific standardized structure that supports customizable questions based on the patient and the medication. This standardization supports a consistent approach to ePA.



States Currently Requiring a Universal ePA Form

The states designated below require or propose requiring the use of a single standard form for all ePA request submissions. State laws requiring use of a single standard form (despite availability of ePA solutions) may lead to more administrative burden. Usually, a single standard form can't address all specific-use requirements for various medications that can arise during the PA process. Nimble ePA solutions provide real-time indicators that may help providers get ahead of PA requirements at the point of prescribing.



Regulatory Developments

Passing legislation often requires policymakers to understand and use healthcare standards developed by Standards Development Organizations (SDOs). SDOs mediate and inform between the legislative and healthcare worlds to ensure comprehensive and consistent implementation and that needs are being met for those directly impacted by policies. For policies directly impacting healthcare technology and medication access, there are a few main SDOs, though this list is not exhaustive.

Health Level Seven International (HL7)

HL7 is a worldwide not-for-profit standards organization for developing framework and standards for exchanging, integrating, sharing and retrieving electronic health information. HL7 is responsible for the development of FHIR and its subsequent versions. HL7 FHIR resources were most recently referenced in the CMS Interoperability and Patient Access Rule as well as the ONC information blocking rule.

HL7 CONSUMER RTPB CHECK

HL7 is currently developing an implementation guide to provide a set of resources for payers to display to consumers via an FHIR API. This resource will be an adaptation of NCPDP's RTPB standard, which was developed for use by prescribers, but will eliminate prescribing-specific process standards to focus on patient-specific cost and coverage information. By providing a patient-specific implementation guide, HL7 establishes an adaptable information exchange for patient-facing technologies, including those that provide differences in copay costs between pharmacies, cash price comparisons and discounts available through manufacturer programs.[39]

National Council for Prescription Drug Programs (NCPDP)

NCPDP is a not-for-profit SDO for healthcare information exchange. NCPDP has developed the SCRIPT Standard for transmitting electronic prescriptions between prescribers, pharmacies, payers and other entities, and the Telecommunication Standard for communication between pharmacy and payer about eligibility verification, claims, services, information reporting, PA and predetermination of benefits, among others.

NCPDP SCRIPT 2017071

In December 2020, CMS issued a final rule that would require Part D drug plans to support the NCPDP SCRIPT standard version 2017071, which improves e-prescribing capabilities for CMS beneficiaries.[40] Under NCPDP SCRIPT Version 2017071, prescribers will be able to see if a Part D-covered drug requires PA while prescribing it and requires providers to supply clinical information electronically before sending a prescription to the pharmacy. Implementation of this standard has been delayed until March 30, 2021.

UPCOMING NCPDP RTPB STANDARD

NCPDP has also been working on a standard for RTPB to potentially be named in 2021, providing industry guidance and liquidity when it comes to patient pricing transparency at the point of prescribing. The standard has been tested in a pilot with Johns Hopkins Medicine. In the six-month study, 98 percent of patients paid less than, the same as, or no more than 3 cents more than the estimate returned by the RTPB transaction initiated by the prescriber.[41] The ONC Final Rule also stated it would consider proposing the NCPDP RTPB standard in future rulemaking regarding interoperability.

Accredited Standards Committee X12

The Accredited Standards Committee X12 is a cross-industry SDO that supports electronic American business transactions and data exchange. While not healthcare specific, X12 standards are used for healthcare transactions other than those within retail pharmacies and are named in HIPAA.

CONCLUSION

Historically, legislation has helped move the needle in healthcare innovation and access. After Medicare and Medicaid went into effect in 1965, 19 million Americans received healthcare coverage who hadn't previously.[42] Today, CMS insures approximately one third of the U.S. population and has helped contribute to a five-year increase in life expectancy and healthier children over the last 50 years.[42] In 1996, HIPAA laid the privacy and standardization groundwork for the digitization of health data to come in the following decade. Thirteen years later, the Health Information Technology for Economic and Clinical Health (HITECH) Act helped dramatically increase EHR adoption, from 3.2 percent in 2008 to 86 percent less than a decade later.[43]

In 2020, however, a public health emergency prompted the next dramatic shift in healthcare, as the industry and government focused all resources on quelling a pandemic.

Federal and state legislators moved telehealth and COVID-19 regulations to the forefront in 2020 out of necessity. And as a result, healthcare is emerging more accessible, modern and patient-friendly.

Healthcare stakeholders, policy makers and SDOs are embracing and advancing policies and standards to reduce provider burden, improve equitable access to patient care and usher in widespread transparency, especially for PA and patient affordability.

As healthcare consumerism continues to expand, these standards and the legislation that includes them can help healthcare IT developers create user-friendly, accessible solutions for unmet or under-addressed healthcare needs. These solutions will help make clear the most affordable options for patients, the path to process expediency and the most equitable resolutions for care team members.

Whether new or temporary regulations stay and the infrastructure to support innovative programs can be built hangs in the queue of chambers and capitols across the country. Interoperability, access issues and implementations will have to take precedence this year, especially for telehealth to remain a permanent option for both government and commercial plans, as it's expected to. For continued growth in medication access, transparency and innovation, supporting legislation and regulation are key.

"We all benefit when the consumer has an understanding of the value of what they're receiving."

–N.Y. ASM. JOHN MCDONALD (D-COHOES)

"Transparency is an essential leg of the stool in creating a free market approach in healthcare and pharmacy in the country."

–SEN. SHANE REEVES (R-BEDFORD, TENN.)

Read more from state legislators across the country who are introducing patient-centered prescription price transparency bills this year in the digital edition of the **Medication Access Report: Legislative and Regulatory.**

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