ASPEN TECH POLICY HUB

POLICY

Improving Medication Access With Better Prior Authorization

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EXECUTIVE SUMMARY

Prior authorization (PA) refers to the process of getting an insurer's approval before a physician provides a treatment.[1] Today, the PA process often harms patients by either delaying care or denying payment for care.[2] Real-time benefit tools (RTBTs), a software product used by healthcare providers when choosing a drug for a patient, have the potential to reduce the harmful effects of PAs for drugs by speeding up the PA process. They do this both by providing real-time PA requirement information to physicians and by enabling patients to avoid PAs altogether.[3] However, RTBTs will need to be improved to meet this potential.

This brief proposes how New York state regulators can improve RTBTs to ultimately reduce the harms caused by PA, and provides sample language for a draft regulation. Specifically, the New York State Department of Health (DOH) can improve RTBTs by adopting regulation to establish the National Council for Prescription Drug Programs Real-Time Prescription Benefit Standard (NCPDP RTPB) as the statewide real-time prescription benefit standard. Currently, because there is no one RTPB standard insurers must follow, insurers provide a wide range of RTBT solutions to healthcare providers. This variability in tools means that providers cannot easily use them consistently.

Requiring all New York insurers to meet the NCPDP RTPB Standard when implementing RTBTs will make those tools more usable and reliable. They will be more usable because the heterogeneous RTBT landscape – which physicians laboriously navigate – will be transformed to a unified experience. And they will be more reliable because the NCPDP RTPB Standard requires insurers to provide cost and coverage information important to patient care, which is omitted by other alternative standards. As a result, physicians will be more

able to use RTBTs to prevent care delays and denials due to PA. This timely policy decision would have the potential to improve millions of administrative and clinical actions that affect patient health outcomes.

PROBLEM

Prior authorization harms patients

PAs can apply to any type of patient care, including lab tests, medical procedures, and drugs. PAs for any of these types of care can harm patients. Results of a 2020 survey conducted by the American Medical Association quantified these harms: 94% of physicians reported that the PA process had delayed care to their patients, and 21% of physicians noted that PA had led to hospitalizations.[4] Delays in PAs reinforce structural inequities to care access among underserved patient populations. Underserved and minority patients disproportionately suffer from chronic conditions, like cardiovascular disease, that require PAs for treatments.[5]

RTBTs can address the harms of PA

Real-time benefit tools are a software product used by healthcare providers when they are choosing a drug for a patient. The Centers for Medicare & Medicaid Services (CMS) describes their purpose as to "make beneficiary-specific drug coverage and cost information visible to prescribers who want to consider that information at the point-of-prescribing."[6]

When physicians prescribe a drug, they follow multiple steps related to prior authorization. These steps are:

1. Determining if a drug requires PA and, when appropriate, searching for alternative prescriptions that do not require PA;
2. Getting clinical and administrative requirements for making a PA request, and then making the request; and
3. Sometimes, if a PA is denied, appealing the decision.

Delays in any of the steps can slow down the timeline for a patient to receive treatment. RTBTs can decrease care delays due to prior authorization by streamlining Step 1 (illustrated in Appendix A). RTBTs can do this by providing real-time PA requirement information and by enabling physicians to prescribe drugs that avoid PAs altogether.[7]

RTBTs have other benefits as well, including increasing the likelihood

that patients finish their prescribed medications, and decreasing costs of care.[8]

RTBTs need to be improved to meet their potential

Unfortunately, several challenges keep providers from realizing the promise of RTBTs:

- **Limited usability.** Today, different insurers provide RTBT solutions that can vary widely from each other. Providers need to learn many RTBT tools and workflows in order to serve their patients.[9]
- **Limited reliability.** RTBT adoption depends on the tools' ability to provide actionable information that physicians trust.[10] There has not been industry consensus around requirements for today's RTBTs, which leads to a concern that these tools "may not always provide useable information."[11]

Because of these issues, providers are not using RTBT tools to their potential and are continuing to rely on slower, more labor-intensive methods to get the benefit information necessary to care for patients.[12]

SOLUTION

The New York State Department of Health (DOH) should enable better patient care by adopting regulation to establish the National Council for Prescription Drug Programs Real-Time Prescription Benefit Standard (NCPDP RTPB) as the statewide real-time prescription benefit standard. If all New York insurers are required to meet the NCPDP RTPB Standard when implementing RTBTs, RTBTs will be more usable and reliable.[13]

We recommend that these RTBT improvements be achieved through regulation because their potential impact warrants a statewide mandate. A draft of the proposed regulation can be found here. The proposed regulation can make RTBTs usable and reliable and, importantly, is feasible to implement now.

Making RTBTs usable

Without a statewide standard, the RTBT landscape is heterogeneous. Historically, because insurers have not been required to follow one standard, their real-time benefit solutions (when they exist) largely fall into several categories of implementations: those using the

NCPDP SCRIPT Standard, those using the NCPDP Telecommunications Standard, and those using custom proprietary standards.[14]

Setting a single standard increases usability by creating a more unified experience for physicians. Right now, across the many insurers they work with, physicians navigate through multiple tools and data formats. Requiring all RTBTs to provide information uniformly across insurers will make them easier to use.[15]

Making RTBTs reliable

A reliable RTBT is one that provides physicians with complete, actionable information that they can trust. According to legislation pending in New York State, SB4620-A/AB5411-A, RTBTs should include the following cost and coverage information to make them reliable:

- "patient-specific eligibility information;"
- "patient-specific prescription cost and benefit data;"
- "patient-specific cost-sharing information that describes variance in cost-sharing based on the pharmacy dispensing the prescribed drug or its alternatives, and in relation to the patient's benefit (i.e., spend related to out-of-pocket maximum);"
- "information regarding lower cost clinically-appropriate treatment alternatives;" and
- "applicable utilization management requirements, such as prior authorization."

The NCPDP RTPB Standard is the only one that meets all of those requirements; alternatives such as the NCPDP SCRIPT Standard and NCPDP Telecommunications Standard do not. For a more detailed comparison of the capabilities of different standards providing real-time benefit information, please see Appendix B.

How has the NCPDP standard been vetted?

The NCPDP RTPB Standard has been vetted through multiple standards development organizations, and would be ready to implement immediately.

- The standard has been approved by standards development organizations. The latest version, Version 12, was approved by NCPDP in October 2021 and by the American National

Standards Institute (ANSI) in September 2021.[16]

- The standard has been piloted with promising results in a study with Johns Hopkins Medicine. The study showed evidence that using the NCPDP RTPB Standard provided information to physicians that enabled cost savings, decreased PAs, and provided accurate price estimates (which can lead to improved medication adherence).[17]
- The standard has been developed through a "multi-stakeholder, consensus-building process," which is inclusive of a broad range of stakeholders.[18] This process included input from insurers that currently use the alternative SCRIPT and Telecommunications implementations, and was designed to make it easier for legacy implementations to be migrated to the RTPB standard.

Why should New York State regulate now?

Every day without a statewide RTPB standard is another day that insurers further commit to RTBT implementations that could compromise patient care. It is urgent for the New York Department of Health to set the NCPDP RTPB standard now because RTBT development is accelerating under recent state and federal policies that do not name a specific standard.

At the state level, SB4620-A/AB5411-A would require all insurers to provide real-time benefit information by July 1, 2023.[19] While this bill has not yet passed, it might quickly follow successful precedent in other states, such as HB1297 in Colorado and SB1617 in Tennessee.[20] Even without SB4620A, New York insurers have already been required to start implementing RTBTs by CMS. CMS-4180-F set a target date of January 1, 2022 for all Part D plan providers to implement RTBTs.[21] As insurers in New York work to comply with this rule, the Department of Health can set the standard that insurers should be working toward in their implementations.

A federal mandate to set a standard for all insurance plans in New York is not expected. While Congress has called on the U.S. Department of Health and Human Services (HHS) to establish an RTBT standard, industry stakeholders expect HHS to set the NCPDP

RTPB Standard for Medicare and Medicaid plans *only*.[22] Thus, action needs to be taken at the state level.

Lastly, setting a standard through regulation rather than legislation also follows healthcare information technology precedent. When states realized the need to establish a standard for a set of electronic prior authorization transactions, state legislation (such as in Iowa and Michigan) did not name a standard, and instead described a process for agencies to choose one. This enables a more agile standards selection process than one fixed in legislation.[23] This makes the DOH an appropriate policymaker for setting a statewide RTPB standard.

CONCLUSION

RTBTs are essential tools that can reduce prior authorization times and improve the quality of healthcare. However, current RTBT tools are ineffective and a burden to healthcare providers. Realizing the full benefits of RTBTs – most notably, decreased care delays and denials due to prior authorization – requires insurers to build better, more standardized tools. A New York State regulation requiring insurers to implement RTBT solutions using the NCPDP RTPB Standard would make those tools more usable and reliable, and would enable physicians to deliver the best possible patient care.

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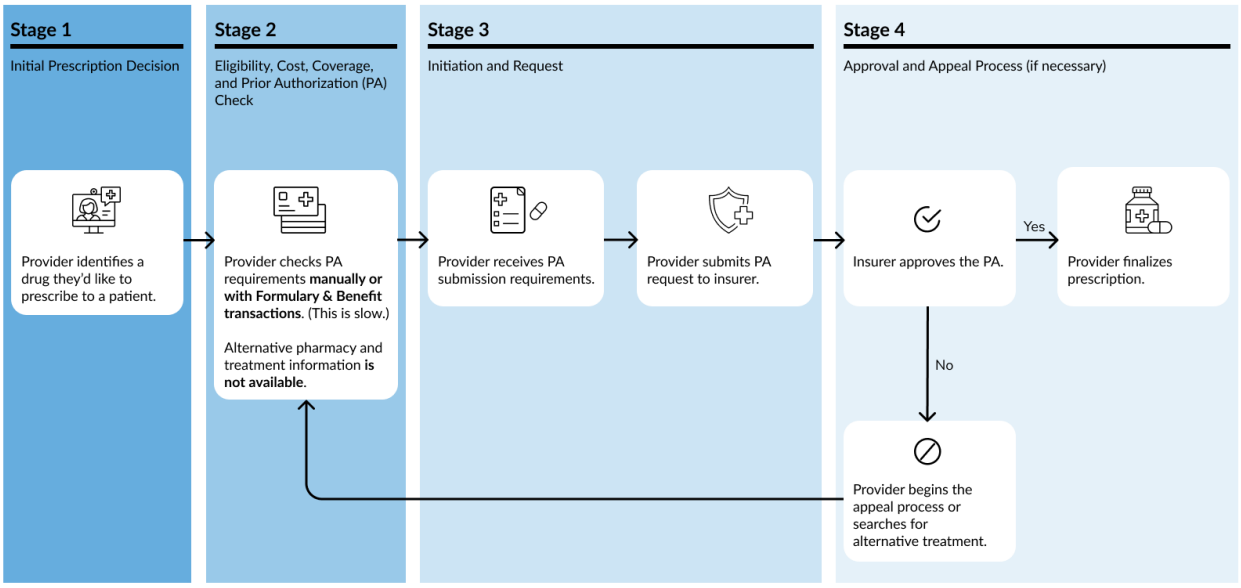
Appendix A: Prior Authorization Process Before and After Real-Time Benefits Tools

Before Real-Time Benefit Tools



After Real-Time Benefit Tools

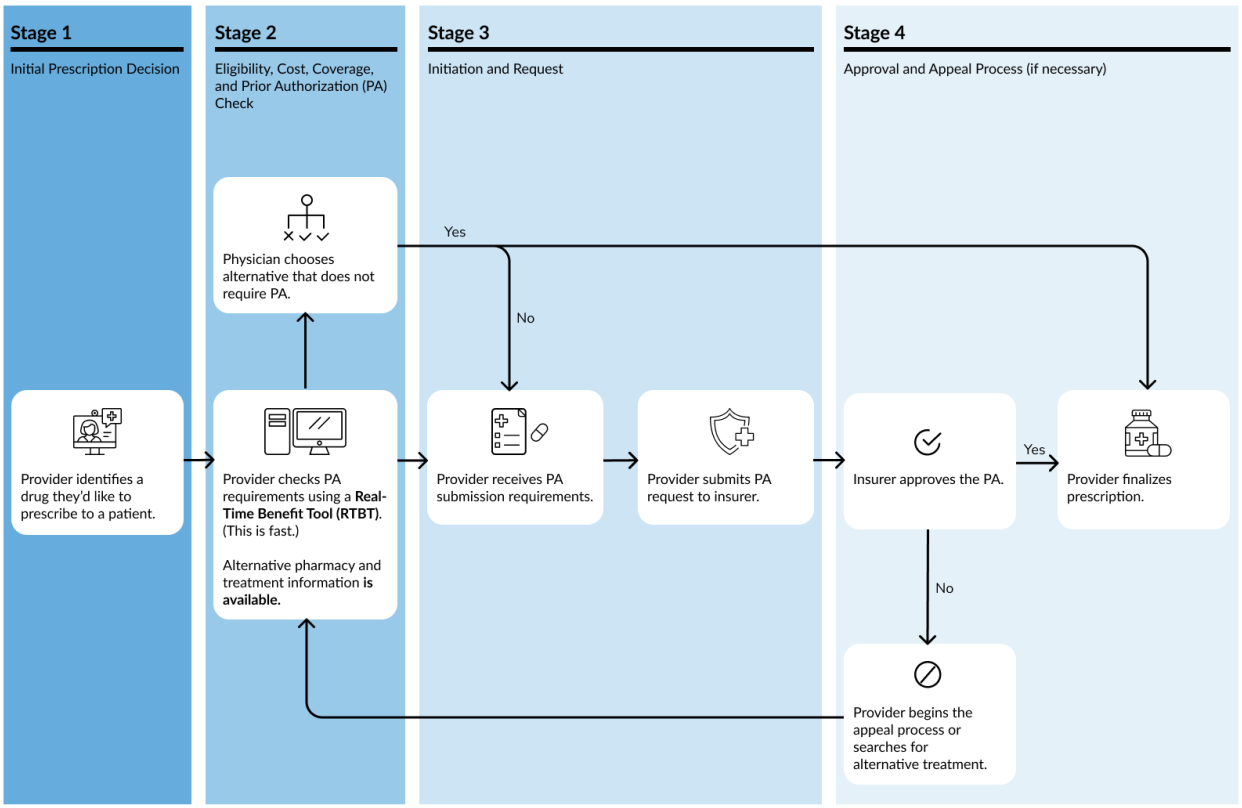


Figure 1

Appendix B

Four standards are used to communicate real-time prescription benefit (RTPB) information. Two standards developing organizations (SDOs) authored these standards: the National Council for Prescription Drug Programs (NCPDP) developed three, and Health Level 7 (HL7) developed one. Both organizations are nonprofits, are accredited by ANSI (American National Standards Institute), and are considered leaders in healthcare interoperability.

The four standards are:

1. **NCPDP SCRIPT Standard**. This standard is used to exchange prescription information, primarily for electronic prescribing and electronic prior authorization. It has been used widely in the industry by prescribers and providers, including as the Centers for Medicare & Medicaid Services (CMS) required standard for Medicare Part D plan electronic prescribing[24] and Part D plan electronic prior authorization.[25] Surescripts, a pharmacy information exchange company, has made proprietary modifications to this standard to support RTPB functionality.[26]

2. **NCPDP Telecommunications Standard.** This standard is used to exchange payment claims-related information, primarily between pharmacies and insurers.[27] DrFirst, a healthcare information technology company, has made proprietary modifications to this standard to support RTPB functionality.[28] However, CMS has acknowledged[29] concerns with using the Telecommunications Standard for the purposes of RTPB.

3. **NCPDP RTPB Standard.** This standard was developed specifically for real-time prescription benefit information exchange between insurers (and entities that provide pharmacy benefit services to insurers), physicians, and other healthcare providers.

4. **HL7 Consumer Real-Time Pharmacy Benefit Check Standard.** Derived from the NCPDP RTPB Standard, this standard provides a subset of the capabilities of the NCPDP RTPB Standard. Specifically, the HL7 standard is designed to support patient-facing RTBTs and so omits some information that physicians would need in an RTBT.[30]

We determined that of those four standards, the NCPDP RTPB Standard is the best one for insurers to use in their RTBT implementations. We reached this conclusion after assessing whether the technical transactions defined in each standard meet a list of RTBT requirements. The list of requirements we

used is taken from SB4620-A/AB5411-A,[31] an RTBT measure in New York State. Each requirement is a category of prescription benefit information that an RTBT should provide.

Table 1 lists one RTBT requirement per row. Each column corresponds with a specific standard. Each cell indicates whether the standard has data fields for the listed RTBT requirement. We made this assessment by analyzing official standards documentation provided by NCPDP and HL7.

If a standard requires modification to meet an RTBT requirement (for example, the Surescripts and NCPDP SCRIPT example listed above), we consider that the requirement is not met. This is because there is not a guarantee that different RTBTs would make consistent, usable, and reliable modifications. Additional context is included in cells where the determinations are less straightforward.

		Standard (as of December 1, 2021)			
		NCPDP SCRIPT Standard *(Version 2017071)*[32]	NCPDP Telecommunications Standard *(Version D.0)*[33]	NCPDP RTPB Standard *(Version 12)*[34]	HL7 Consumer Real-Time Pharmacy Benefit Check Standard *(Version 1.0.0)*[35]
Does the standard meet this requirement?	Patient-specific eligibility information	No. The documented workflow suggests using a combination of Formulary & Benefit[36] and X12 270/271[37] requests for eligibility, which have limited success.[38]	Some. The information exchange is designed for communication between payers and pharmacies, rather than providers.[39]	Yes	Yes
	Patient-specific prescription cost and benefit data	No	Some. Relevant fields are available only through claims communications.[40]	Yes	Some. "Cost to plan" data are omitted.
	Patient-specific cost-sharing information across different pharmacies	No	No	Yes	Yes
	Information regarding lower cost, clinically appropriate treatment alternatives	No	No	Yes	Yes
	Applicable utilization management requirements	Some. Limited prior authorization information can be retrieved in PA Initiation Response messages.	Some. Prior authorization information is limited to claims and "pharmacy to plan" transactions.[41]	Yes	Some. Drug utilization review (DUR) information is missing.

Endnotes

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