

## Compliance Today – January 2022

### Improve member experience with real-time benefit tools and drug price transparency

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With nearly half of all Americans using prescription drugs<sup>[1]</sup> and drug costs rising at a rate exceeding national inflation,<sup>[2]</sup> vulnerable Americans are made more vulnerable by high drug costs. Most of the time, patients do not know the cost of their drugs until they are charged at the drug counter. Several studies document that patients are prone to abandon their prescriptions<sup>[3]</sup> or underdose themselves in order to have money for other important expenses, such as food and rent. In 2019 alone, Americans collectively paid \$67 billion out of pocket for prescription medications,<sup>[4]</sup> with 45% of people abandoning their scripts when out-of-pocket costs exceeded \$125. Unfilled prescriptions and patient underdosing are not only dangerous to patients—they create considerable compliance risks for providers and health plans.

As out-of-pocket expenses increase, medication adherence decreases, especially for those on multiple medications and of lower socioeconomic status.<sup>[5]</sup> The long-term benefits of medication adherence—improved clinical outcomes and decreased costs—are blunted when drug affordability trumps drug adherence. Unfortunately, providers who prescribe medications rarely have drug cost information to consider when prescribing, and the pharmacist who sees the cost rarely has the ability to easily change the prescription to a therapeutic equivalent.

### Real-time benefit tools

Over the past few years, the federal government has attempted to address one of the largest factors driving overall healthcare costs—prescription drugs<sup>[6]</sup>—by creating measures to increase the power of market forces in the drug supply chain and to establish drug price transparency. The Trump administration proposed a number of ambitious initiatives, including the removal of the safe harbor protection for drug rebates, establishing an international price index for Part B drugs, drug importation from Canada, and requiring a drug maker to list a drug's list price in television ads.<sup>[7]</sup> For a variety of reasons, these ambitious drug-pricing reforms have not been implemented.

Ultimately, it may be one of the less prominent drug-pricing reforms from the last administration that proves the most consequential. Per regulation, the Centers for Medicare & Medicaid Services (CMS) Contract Year 2022 Medicare Advantage and Part D final rule requires Medicare Part D stand-alone plans and Medicare Advantage plans offering Part D to offer a real-time benefit tool (RTBT)—a web-based platform that displays lower-cost and therapeutically equivalent options for any on-formulary prescribed drug.<sup>[8]</sup> RTBTs can be viewable to prescribers and beneficiaries. Already in effect as of January 2021, plans offering Part D must have adopted a

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provider-facing RTBT that furnishes complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information to the prescriber in real time.<sup>[9]</sup> This permits a provider to consider pricing when making prescribing decisions. While the rule only requires the platform to be integrated with a singular network prescriber's electronic health record or electronic prescribing system, this is the first step in providing drug transparency at the point of care.

The second step in RTBT implementation may prove more important. The beneficiary drug price transparency tool goes into effect January 1, 2023.<sup>[10]</sup> Plans must provide a beneficiary-facing RTBT that gives beneficiaries access to their formulary and benefit information via a portal or computer application. The RTBT must include cost-sharing options so beneficiaries can view lower-cost, clinically appropriate therapies within their plan's formulary. This will empower a cost-sensitive beneficiary, for the first time, to discuss financial concerns with prescribers at the moment the prescription is written. Medicare beneficiaries, millions of whom continue to incur cost sharing even after reaching the "catastrophic threshold" in the Part D benefit,<sup>[11]</sup> can now know their costs before reaching the pharmacy counter and can request cheaper alternatives from their prescribers. Subject to certain standards, the Part D sponsor may provide rewards and incentives to enrollees who use the beneficiary RTBT—an important departure from long-standing Part D policy.<sup>[12]</sup>

## Transparency in coverage regulation and prescription drug costs

Yet another rule will come into effect that could similarly empower patients to actively shop for lower-price prescription drugs. Finalized by the departments of Health & Human Services, Labor, and the Treasury in November 2020, the Transparency in Coverage rule applies to group health plans and health insurance issuers in the individual and group markets.<sup>[13]</sup> As it relates to member-facing price transparency tools, a self-service out-of-pocket cost estimator will be required in two phases:

- By January 1, 2023, plans and issuers must provide out-of-pocket cost estimates for 500 shoppable items and services in an internet-based, self-service tool for members, in addition to in-network rates and out-of-network allowed amounts.
- By January 1, 2024, cost estimates, in-network rates, and out-of-network allowed amounts for all covered items and services, including prescription drugs, must be available in the self-service tool.<sup>[14]</sup>

While retail prescription drugs were generally excluded from the January 2023 requirement, plans and issuers may incorporate prescription drug cost estimates sooner than the January 2024 deadline. Given the rollout of the Part D RTBT requirement in January 2023, a plan or issuer operating in both Part D and commercial markets may very well choose to implement both at the same time given the relationship between affordability and medication adherence and potential for savings for both the member and the plan.

Why would a plan or issuer seek to bring up these drug price transparency tools early? Simply put, they create a win-win scenario for the plan and its members, with both parties saving money by steering a member toward a cheaper, clinically equivalent drug. In just one example, Rx Savings Solutions, operating a RTBT for a regional plan between 2018 and 2020, saved members \$4.1 million while saving the plan another \$12.7 million.<sup>[15]</sup>

## Are plans ready to comply?

This summer, Rx Savings Solutions conducted a survey that assessed health and drug plans' readiness and understanding of the RTBT and transparency-in-coverage requirements. The short answer is that many plans are not ready.

Of the more than 300 survey respondents (professionals from health and drug plans), when asked if they were familiar with the CMS Transparency in Coverage ruling, 51% were largely unfamiliar with it, and 40% did not understand the impact of the regulation for their organization. Less than half (43%) recalled receiving communication from their organizations on how their plan expects to become compliant with the requirements. Although a quarter (25%) of respondents felt “completely” confident that their organization would meet the new requirements, the top challenges identified are formidable. They include:

- Lack of access to necessary data,
- Limited time frame to implement the requirements, and
- Concerns with interpretations and understanding of the requirements.

Most survey respondents believe that their plan will have to rely on external experts. Respondents suggested that they would obtain help from pharmacy benefit managers, third-party administrators, member engagement vendors, consultants, and others. And there is a silver lining to these generally concerning findings: A large majority (74%) of survey respondents plan to use the coming requirements as an opportunity to provide additional value to their members (e.g., price transparency, enhanced member experience).

Based on CMS estimates, the adoption of a beneficiary RTBT will cost Part D plans about \$4 million for all plans in the first year based on the costs for them to reprogram their computer systems.<sup>[16]</sup> This cost will be divided among the hundreds of Medicare Advantage and stand-alone Part D sponsoring organizations. Against this modest investment is the penalty for not complying, which might include civil money penalties and enrollment sanctions (although initial leniency is probable).

So, while plans and issuers have win-win incentives to stand up drug price transparency tools, the survey results suggest that information gaps are working against proactivity, and plan budget cycles limit the opportunities for plans to invest in new tools. External experts will be consulted and may fill information gaps, but they will not build the tool for a plan or issuer. There are very few field-tested, savings-generating RTBTs that meet the regulatory requirements. So, when plans and issuers consider establishing an external partnership, they should be cognizant of the time it will take to identify a suitable, compliant vendor given so few viable solutions are on the market.

## Looking ahead

As health and drug plans assess their internal capabilities and evaluate external resources to help them meet the new RTBT and Transparency in Coverage requirements, there is much to consider. Given the nuances of plan tiers and formularies, the RTBT will need robust capability to analyze the enrollees’ drug benefits and to list alternative substitutes, all while on the front end showing an easy-to-use interface design that a Medicare beneficiary, usually someone who is older, can seamlessly navigate. Similarly, the Transparency in Coverage self-service tool should be easily accessible and provided in a manner that helps members take actions to leverage the estimate by sharing information on how to fulfill a lower-cost prescription at the pharmacy counter or through mail order, for example. Drug pricing transparency may very well become a boom industry, but few organizations will have time-tested tools that can document that they meet regulatory requirements while driving savings to both plans and patients.

## Takeaways

- Real-time benefit tools (RTBTs) provide information on the lowest-cost clinically appropriate drug at the time the prescription is written.

- Medicare Advantage and Part D plans are required to offer RTBTs with a requirement to offer an RTBT to all plan members on January 1, 2023.
- Centers for Medicare & Medicaid Services' Transparency in Coverage regulation puts commercial health plans on a path toward a required cost-estimator tool (similar to RTBT) by January 1, 2024.
- These tools provide an opportunity to lower the cost of drugs for both health plans and their members.
- Particularly for Medicare plans facing an earlier deadline, Medicare Advantage and Part D plans should be actively moving toward meeting RTBT requirements.

**1** Crescent B. Martin, Craig M. Hales, Qiuping Gu, and Cynthia L. Ogden, "Prescription Drug Use in the United States, 2015–2016," NCHS Data Brief No. 334, National Center for Health Statistics, Centers for Disease Control and Prevention, May 2019, <https://www.cdc.gov/nchs/products/databriefs/db334.htm>.

**2** Stephen W. Schondelmeyer and Leigh Purvis, *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2020*, Rx Price Watch Report, AARP Public Policy Institute, June 2021, <https://www.aarp.org/content/dam/aarp/ppi/2021/06/trends-in-retail-prices-of-brand-name-prescription-drugs-widely-used-by-older-americans.10.26419-2Fppi.00143.001.pdf>.

**3** "Medication Access Report," CoverMyMeds, accessed November 15, 2021, <https://www.covermymeds.com/main/medication-access-report/>.

**4** IQVIA, *Medicine Spending and Affordability in the U.S.: Understanding Patients' Costs for Medicines*, August 4, 2020, <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us>.

**5** Kaiser Family Foundation, "Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines, including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age," March 1, 2019, <https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/>.

**6** Eric M Tichy et al., "National trends in prescription drug expenditures and projections for 2020," *American Journal of Health-System Pharmacy* 77, no. 15 (August 1, 2020), <https://academic.oup.com/ajhp/article/77/15/1213/5837520?login=true>.

**7** Tom Bulleit, Deborah Gardner, and Scott Falin, "The Trump Administration's Latest Drug Pricing Initiatives," *Ropes & Gray*, January 15, 2019, <https://www.ropesgray.com/en/newsroom/alerts/2019/01/The-Trump-Administrations-Latest-Drug-Pricing-Initiatives>.

**8** Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 85 Fed. Reg. 5,864 (January 19, 2021), <https://www.federalregister.gov/documents/2021/01/19/2021-00538/medicare-and-medicare-programs-contract-year-2022-policy-and-technical-changes-to-the-medicare>.

**9** 42 C.F.R. § 423.160(b)(7) .

**10** Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 85 Fed. Reg. 5,864 .

**11** Chris Lee, "Millions of Medicare Part D Enrollees Have Had Out-of-Pocket Drug Costs High Enough to Exceed the Catastrophic Threshold Over Time," news release, Kaiser Family Foundation, July 23, 2021, <https://www.kff.org/medicare/press-release/millions-of-medicare-part-d-enrollees-have-had-out-of-pocket-drug-costs-high-enough-to-exceed-the-catastrophic-threshold-over-time/>.

**12** 42 C.F.R. § 423.128(d)(4), (5) . This information must also be available through the plan's call center.

**13** Transparency in Coverage, 85 Fed. Reg. 72,158 (November 12, 2020) ,

<https://www.federalregister.gov/documents/2020/11/12/2020-24591/transparency-in-coverage>.

**14** 26 C.F.R. § 54.9815-2715A 2(b); 29 C.F.R. § 2590.715-2715A 2(b); and 45 C.F.R. § 147.211(b) . Under 26 C.F.R. § 54.9815-2715A 3; 29 C.F.R. § 2590.715-2715A 3; and 45 C.F.R. § 147.212 of the Transparency in Coverage regulation, plans and issuer must also post, among other data, the in-network rates, out-of-network allowed amounts and billed charges, and historical prescription drug prices in three machine-readable files by January 2022. (Note: through subsequent guidance, the federal enforcement deadline was extended to July 2022; states may choose to enforce as of January 2022 for state-regulated fully insured plans.)

See <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf>. While these files will not be usable for the average enrollee, third-party app developers can use the data to develop consumer-friendly look-up tools, and researchers can use the data to perform analyses.

**15** Compiled from Rx Savings Solutions internal reports. Extract available on request.

**16** Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 85 Fed. Reg. 6,087 .

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