January 14, 2019

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services, Attention: CMS-4180-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses," CMS-4180-P

Dear Regulations Staff:

Point-of-Care Partners (POCP) is pleased to provide the Centers for Medicare and Medicare Services (CMS) with comments on Section 2 of the subject draft rule, "E-prescribing and the Part D Prescription Drug Program; Updating Part D e-prescribing Standards." In this section, the rule proposes requiring Part D plan sponsors to implement an electronic real-time benefit "tool" (RTBT) capable of integrating with prescribers' ePrescribing and electronic medical record (EMR) systems.

POCP is uniquely positioned to comment on this proposed requirement. We are a nationally recognized consulting firm in the areas of electronic prescribing (ePrescribing); standards to support payers, prescribers and pharmacies; specialty pharmacy automation; electronic exchange of health and administrative data; interoperability of electronic health records (EHRs); and electronic medication management. POCP also provides related management and strategic consulting services in those areas to a wide range of stakeholders.

Since 2006, POCP has been a leader in the development of standards and transactions being adopted under the Health Insurance Portability and Accountability Act (HIPAA) and Medicare Part D. We have testified frequently before the National Committee on Vital and Health Statistics (NCVHS), as well as provided technical assistance to both CMS and the Office of the National Coordinator for Health Information Technology (ONC).

Most recently, POCP has been at the forefront of the development of standards for electronic prior authorization (ePA) and the Real-Time Pharmacy Benefit Check (RTPBC). We currently are helping to lead a multi-stakeholder effort for use of HL7's FHIR (Fast Healthcare Interoperability Resources) standard to facilitate the exchange of clinical and administrative data among payers in support of value-based care. FHIR also shows promise for the development of application programming interfaces (APIs) for patients to access their data and better understand their financial liability for their health care and treatments.

Point-of-Care Partners' Comments on Section 2 of the Draft Rule, "E-prescribing and the part D prescription drug program; updating Part D e-prescribing standards." Our comments fall into two categories, as described below.

I. Comments on the requirements of the proposed regulation as set forth in Section 2:

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1. Name of the transaction. The proposed rule references a Real-Time Benefit Tool. We believe the term "tool" is a misnomer. To some, it refers to proprietary implementations currently in the market, and could be misinterpreted as a piece of software.

In reality, what is being developed is a transaction specification, which will be adopted by industry stakeholders. The transaction in question is one in the ePrescribing process that is referred to in the industry as a Real-Time Benefit Check (RTBC). Point-of-Care Partners believes it should be called the Real-Time Pharmacy Benefit Check (RTPBC). That is because the transaction refers to an electronic benefit check for drugs covered under the patient's pharmacy or prescription benefit. It is distinct from a similar transaction for checking benefits for drugs, devices, and procedures covered under the patient's medical benefit. The industry is beginning work on what could be called a real-time medical benefit check (RTMBC).

- **Recommendation 1a:** We recommend that the final rule refers to the real-time benefit check as a transaction rather than a tool.
- **Recommendation 1b**: We recommend that CMS adopt the term Real-Time Pharmacy Benefit Check (RTPBC) to prevent confusion and eliminate the need for additional nomenclature changes when the Real-Time Medical Benefit is under consideration for use by Part B in the near-term horizon.

2. Electronic health record. The draft rule refers to the integration of the RTPBC within the prescriber's ePrescribing system and electronic medical record (EMR); yet, ePrescribing systems are now part of electronic health records (EHRs), not EMRs. According to the Office of the National Coordinator for Health IT (ONC),[1] the distinction between EMRs and EHRs is as follows:

- Electronic medical records (EMRs) are ***digital versions of the paper charts*** in clinician offices, clinics, and hospitals. EMRs contain notes and information collected by and for the clinicians in that office, clinic, or hospital and are mostly used by providers for diagnosis and treatment.
- Electronic health records (EHRs) are built to go beyond standard clinical data collected in a provider's office and are inclusive of a broader view of a patient's care. EHRs contain information from ***all the clinicians involved in a patient's care***.

In addition, use of EHR would align with CMS' use of "Certified Electronic Health Record Technology" referenced in Promoting Interoperability (PI) Programs.

- **Recommendation 2a:** We suggest CMS change the language to reflect the integration of the ePrescribing system within the electronic health record (EHR).

3. Implementation date. The proposed implementation date is January 1, 2020. This is a transaction that primarily flows from provider (using an EHR) to a payer, generally through an intermediary. We observe that some payers, providers, and EHR vendors would consider this to be a very aggressive timeframe.

[1] https://www.healthit.gov/faq/what-are-differences-between-electronic-medical-records-electronic-health-records-and-personal.

On the other hand, some would say the proposed implementation date is achievable, given the number of solutions in the marketplace already by such vendors as CoverMyMeds, DrFirst, RxRevu, Surescripts, Gemini Health, Allscripts, Athena, NewCrop, among others. In fact, some payers/PBMs who currently offer an RTPBC solution have publicly stated their RTPBC solution complies with the NPRM (CMS-4180-P) as it is written.

In a recent **Data Brief**, Surescripts noted that there were 8.5 million RTPBC transactions flowing through its network in October 2018. That said, this is just one example of an industry RTPBC solution already available to prescribers.

Crucial to this transaction are EHRs. There is still a dependency on them to integrate RTPBC into their solutions for optimal workflow. Adding in the RTPBC is not on every EHR developer's schedule at this point in time. In addition, the RTPBC is not part of ONC's EHR Certification criteria, so vendors may not be paying attention to it.

In summary, given a myriad of other software enhancements that vendors need to address, it will be challenging for all vendors to implement RTPBC by 1/1/20, especially since standards are not yet finalized.

- **Recommendation 3a**: We recommend that ONC adds the RTPBC to the required functionalities for its EHR Certification.
- **Recommendation 3b**: We recommend that CMS consider moving back the proposed implementation date to give vendors an opportunity to build to the transaction.

4. Use of standards. The proposed rule is agnostic in terms of a standard to be used for the RTPBC. In the past, the lack of a clearly identified, candidate standard at the time of rulemaking has created downstream challenges related to implementing and updating HIPAA standards.

The draft regulation indicates that if an RTPBC standard is available in a year or so, it could be adopted by Part D for 2021. Currently, there are several implementations available for RTPBC transactions. The most frequently used by early adopters are based on two standards from the National Council for Prescription Drug Programs (NCPDP): NCPDP SCRIPT 2017071 and NCPDP Telecommunications version 3.2. An NCPDP workgroup currently is assessing standards needs for RTPBC, with a possible standard ready for balloting in November 2019.

- **Recommendation 4a:** Because we believe that a single standard will hasten adoption of RTPBC and eliminate the potential for an unsustainable number of one-off solutions, it is our recommendation that CMS require use of a single standards-based RTPBC transaction that is deemed most appropriate by NCPDP.
- **Recommendation 4b**: If CMS decides to name a particular standard and version, it should do so with an eye toward syncing updates with forthcoming requirements from ONC and recommendations from the National Committee on Vital and Health Statistics (NCVHS). ONC is seeking public comment on its recently released draft *Strategy on Reducing Burden Relating to the Use of Health IT and EHRs*. The Strategy is designed to reduce administrative and regulatory

burdens associated with the health information technology infrastructure, such as standards versioning and updates. NCVHS is concluding its work on ways to speed up the standards adoption process and will be forwarding its recommendations soon to CMS.

- **Recommendation 4c**: If a particular standard is selected, CMS should require the development of a standard implementation guide to ensure consistent, industry-wide execution.

5. Address the relationship with formulary and benefit files. The proposed rule does not address the interaction between and RTPBC and the formulary and benefit (F&B) standard, also maintained by NCPDP. This is an important issue and needs to be clarified in the final rule.

Since the early 2000s, F&B is a data file standard used to provide formulary and benefit information about drugs approved for reimbursement by payers and pharmacy benefit managers (PBMs). This information can then be used in the ePrescribing process to help the prescriber determine whether the drug in question is on formulary and whether a prior authorization is needed.

That said, there are some caveats. First, this information is not available for all patients. Surescripts notes that its Master Patient Index covers about 71% of the US population.[2] Second, there are several challenges with current Formulary & Benefit data, including:

- Formulary data is based on "plan-" or "group"-level; not patient-specific
- The Prior Authorization flag often missing or inaccurate
- Formulary tier/preferred level often not accurately displayed for the health care provider

Some believe that the RTPBC will replace the need for F&B files. Others believe the need for F&B files will not go away with the advent of RTPBC. Rather, F&B will evolve to support RTPBC by consistently alerting prescribers of the need to perform a RTPBC due to mitigating factors, such as noncovered drugs. Thus, eligibility-informed formulary is still important because it helps determine whether an RTPBC is needed.

For this to work well, however, two things have to happen. First, payers have to populate the prior authorization field in the F&B file and make it available in the RTPBC response. Data in this PA field is frequently missing or inaccurate. Even when the flag is provided, the need for PA is not always accurately presented. In the case of RTPBC, it can more accurately represent member-specific benefits.

Second, payers must address the gaps in F&B data. For example, key data often are missing regarding individual patients' insurance coverage, coverage restrictions, therapeutic class guidelines, and deductibles. Currently, these data are not always presented completely or accurately, which is why they are not trusted by many prescribers. Such problems serve as a barrier to adoption.

[2] https://surescripts.com/docs/default-source/national-progress-reports/2151_npr_2017_finalB.pdf

- **Recommendation 5a:** CMS should require payers to provide a minimum mandatory data set to populate F&B files.
- **Recommendation 5b:** CMS should require payers to populate the prior authorization field in F&B files.
- **Recommendation 5c:** The final rule should specify that the RTPBC does not replace the eligibility-informed F&B check.

II. Comments related to implementations of RTPBC to make it more useful, accurate, and complete in addressing price transparency and patients' out-of-pocket financial obligations.

6. Establish a uniform patient out-of-pocket cost model. Because of the way RTPBC has evolved, there are varying models for patient out-of-pocket costs.

- **Recommendation 6a:** CMS should work with industry to create a uniform patient out-of-pocket cost model. This is needed to ensure that payers provide consistent and uniform out-of-pocket cost information.

7. Address the prescription rework challenge. Another challenge associated with the use of the RTPBC is the prescription rework challenge. One **study** confirms that prescribers using the RTPBC frequently change the drug prescribed when provided with information regarding a patient's insurance coverage and out-of-pocket (OOP) costs. When that happens, the prescriber is faced with extra steps when selecting an alternative, whether it's for an entirely different medication or just a change in packaging and strength. This is a hassle and one reason why so many prescribers just say, "Let the pharmacist sort it out." How does that happen today? It's often resolved by phone; many physicians perceive it as easier to have a nurse answer the phone than to rewrite a prescription. In any case, any rework takes precious time away from the patient visit and adds to physician dissatisfaction. To ensure broad adoption and sustained use of RTPBC, CMS, ONC and others must address interoperability between the EHR system's ePrescribing system and RTPBC application. This must be carefully designed and implemented to pass RTPBC results as a new prescription to eliminate clinician rework.

8. Integrate additional cost/access information. There also are information gaps affecting patients' potential out-of-pocket liability. It begins with copay, which can vary by medication, patient, and plan. There is also financial assistance offered by manufacturers, foundations, and states. For example, many manufacturers fund coupon and copay card programs to offset the costs of drugs for consumers. In fact, manufacturers offer **coupons** for nearly half of the top 200 drugs, creating billions of dollars in potential savings opportunities. They also fund financial assistance for patients' drug copays or other medical expenses through nonprofit foundations. Many **states** have similar programs, although details vary as to for whom and what conditions may be covered. Several payers also offer drug assistance programs, such as **CVS Health** and Express Scripts' **InsideRx**. Having this kind of information at the point of prescribing can help the physician identify more cost-effective options for the patient. This ultimately improves outcomes and medication adherence and reduces costs.

- Recommendation 8a: CMS should require RTPBC to provide lower-cost alternatives and restrictions, such as requiring a specific pharmacy.

CMS could also encourage industry to provide relevant information on payment assistance programs. This will help ensure that patients and prescribers have the most complete picture of costs and availability associated with a particular medication. Research has shown that medication unaffordability is a major barrier to medication adherence.

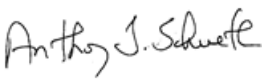
9. Enable RTPBC access for patients. Today, patients often do not fully understand the cost of new medication therapy until they arrive at the pharmacy, and in some cases, cannot afford it. If patients had access to RTPBC, they could have full visibility into their and family members' medication costs, alternatives, restrictions (eg, prior authorization), assistance programs and pharmacy options prior to arriving at the pharmacy. Once payers build RTPBC for providers, it would be feasible to allow patients to access the same data via portals or apps.

- Recommendation 9a: CMS should consider including patient-facing implementations of RTPBC for payers.

Conclusion. Point-of-Care Partners is pleased to offer comments on the proposed regulation. Please do not hesitate to ask for clarifications or additional information. You can reach me at tonys@pocp.com.

Thank you for the opportunity to comment on this draft regulation.

Sincerely,



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