Testimony of

Pooja Babbrah
Senior Consultant
Point-of-Care Partners, LLC

For

Special Committee on Aging
United States Senate

March 7, 2019

Mrs. Chairman, Ranking Member Casey and members of the Special Committee, thank you for inviting me to testify before your committee. My name is Pooja Babbrah. For over two decades, I have had the pleasure of working in the healthcare technology industry, primarily in the areas of electronic prescribing (ePrescribing) and eMedication Management. I started my career working for a pharmacy benefit management (PBM) company and was involved in the very early days of ePrescribing when it was first introduced to the market in the late 1990s. We have certainly come a long way since then with availability of computerized tools and information available at the point of prescribing to help physicians choose the most effective, appropriate and cost-effective therapy for their patients. I'm currently a senior consultant for Point-of-Care Partners, the leading management consultancy in ePrescribing, ePrior Authorization and formulary management. We assist a wide range of healthcare organizations to develop and implement winning health information management strategies and manage integral programs, all of which are evolving in a rapidly changing technology-driven world.

Point-of-Care Partners has been involved with real-time pharmacy benefit check (RTPBC) since early 2014. We appreciate the opportunity to provide background and insights into the current tools, standards and technology being used in the industry to bring real-time pharmacy benefit information to physicians and to address the need for this information to be accessible directly to patients to help them navigate the prescription drug landscape.

Value of Real-Time Pharmacy Benefit Check for Prescribers and Patients

We are here today to talk about price transparency and, while RTPBC can provide prescription drug out-of-pocket costs to providers, pharmacists and patients, it's important for Committee members to understand its value beyond that. RTPBC is a transaction standard being developed by the National Council for Prescription Drug Programs (NCPDP), the preeminent American National Standards Institute

(ANSI)-accredited standards development organization (SDO) for prescription transactions in the ambulatory, long-term care and post-acute care settings. RTPBC will not only show patient out-of-pocket costs, it will also give prescribers and patients cost effective alternatives to the prescribed medication along with insights into requirements by the insurance company including any prior authorization (approval by the payer), quantity limits (parameters on the number of pills a patient can get) or step therapy requirements (where a payer wants a patient to try other medications prior to the one that was prescribed). Using RTPBC, the prescriber or patient may also be alerted to the least expensive place to fill a prescription. The goal is to provide more accurate information about a patient's prescription coverage and the cost of their medications at the point of prescribing, to help avoid sticker shock at the pharmacy counter and potentially delays in starting or continuing a patient's treatment.

Studies have shown that cost is the number one reason for prescription abandonment (provider prescribes but patient does not fill the prescription) and non-adherence (patient fills the prescription and then takes a partial dose to extend the amount of medication because it is so expensive to refill). By providing insight into the cost of medications to the prescriber, we believe that RTPBC will enable prescribers to ensure that the prescriptions that get written are actually filled, and that patients take them as prescribed – greatly improving public health.

There are a few shortfalls with RTPBC as it is being deployed today, including the lack of information about potential cost-savings, discount programs and other financial support programs. It is also important to note that RTPBC is limited today to only those transactions covered by the pharmacy benefit. Some specialty medications are covered under the medical benefit, and pricing for those medications are not available with the current RTPBC transaction. Use of the RTPBC is limited in scope between PBMs and prescribers through their EHRs. We believe that it is important to expand the reach of RTPBC to additional stakeholders including the patient and patient's caregiver. Finally we believe that RTPBC should be expanded to also incorporate additional information related to the patient out-of-pocket cost for the drug. Specifically, patients and patient caregivers should have information that will help them determine whether they should obtain a prescribed medication under their prescription benefit or by paying the cash price. All stakeholders should also have access to pricing information for the pharmacies in their network that highlights where they can access the lowest negotiated price under insurance coverage or lowest cash price.

Tremendous progress has been made with the development and utilization of RTPBC. To date, the business cases for RTPBC have been driven primarily by the benefits to payers/PBMs and providers. We are confident that widespread use of RTPBC will yield a public health gain while at the same time enabling patients to receive their medications at the lowest possible cost.

History of Real-Time Pharmacy Benefit Check

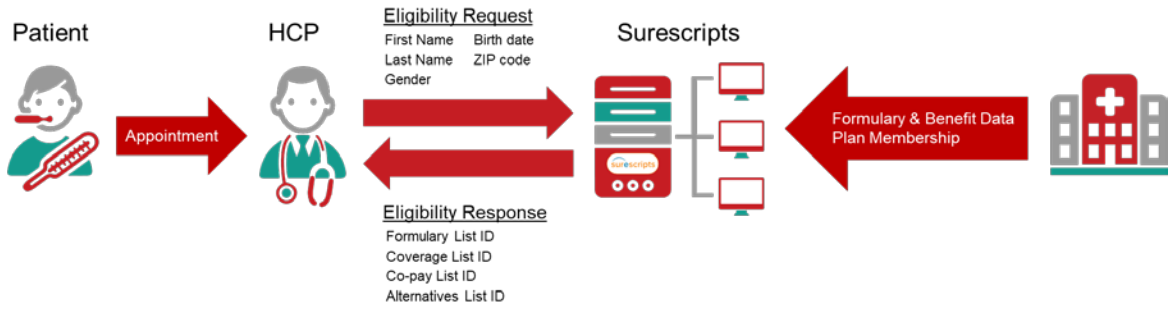
To give the committee a comprehensive overview of RTPBC, I believe it would be instructional to start with some history. The Office of the National Coordinator (ONC) for Health IT's Notice of Proposed Rule Making (NPRM) released in February 2014 was the catalyst for industry efforts around RTPBC. At the

time, ONC was soliciting comments to ask a fundamental question, "Why can't the same information that is being presented at the pharmacy point-of-sale (POS) -- the term the industry uses for the pharmacy -- be presented at the point-of-care (POC)?"

This request was made by ONC in response to prescriber-identified challenges with formulary and benefit (F&B) information being presented in electronic health records (EHRs) today. Since the 1990s, health plans and PBMs have been providing formulary and benefit information on drugs covered under the pharmacy benefit to prescribers. Since the turn of the century, EHRs have used the NCPDP F&B standard, a flat file that has certain defined elements and a comprehensive set of structured data element fields.

F&B was created at a time when doctors had neither high-speed internet in their offices (to tap into the real-time information being presented at the POS) nor incentives to prescribe electronically. Physicians believed at the time that prescribing electronically would be slower than writing paper prescriptions, so F&B was created in a manner that wouldn't slow the prescriber.

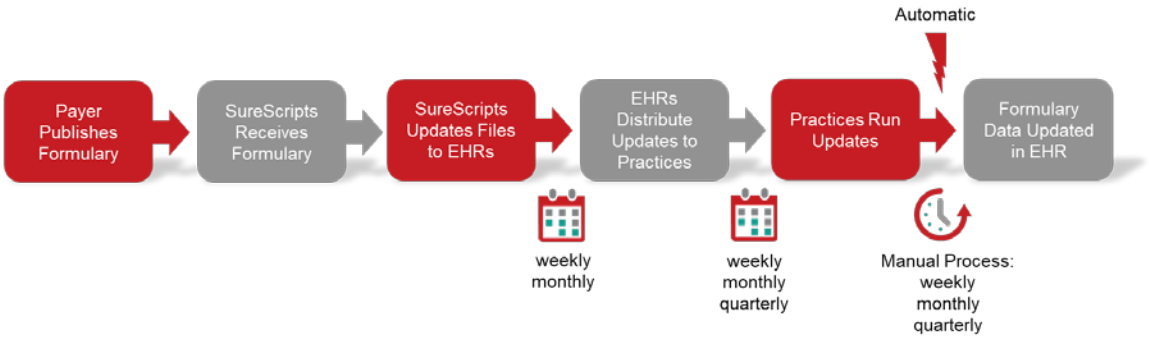
The process of leveraging F&B begins with an eligibility check that is run from the EHR, the response to which contains the identifiers to link the patient to the appropriate formulary that is provided in a separate transaction. (We in the industry call this "eligibility-informed formulary.") This information is, then, presented to the prescriber.



The source of this formulary and benefit information is pharmacy claims, dispensed prescription data and the pharmacy benefit management's benefit rules engine.

On the claims side, today pharmacy benefit management (PBM) companies extract formulary information from their claims systems, aggregate this data, add benefit information and rules, put it into the F&B standard and provide it to the largest ePrescribing intermediary, Surescripts. Several of the retail pharmacies also provide feeds of dispensed medications to Surescripts. Surescripts does quality control to the degree it can, aggregates this data and provides it electronically to their contracted EHR and ePrescribing vendors, of which there are nearly 700 such applications certified by Surescripts to display portions of this information to prescribers.[1] In 2017, Surescripts delivered more than 1.74 billion ePrescriptions, and its network included a provider directory of 1.47 million and a master patient index of 233 million patient.[2]

[1] Surescripts Certified e-Prescribing and EHR Software for Providers, accessed March 4, 2019 at https://surescripts.com/network-alliance/eprescribing-prescriber-software/.
[2] Surescripts 2017 National Progress Report.



The F&B standard was tested in the 2006 ePrescribing pilots and recommended by pilot testers in a 2007 report to Congress.[3,4] Medicare Advantage and PDP plans were mandated to use this and other standards by April 2009.[5]

While F&B is a key standard for the industry which is continually being improved, it also has its shortcomings.

Shortcomings of Formulary and Benefit

Perhaps the largest shortcoming stems from the flat file-aggregation process. Because of it, the information being presented to the prescriber is a "snapshot in time," meaning it was likely accurate as of the day the flat file was created but may not be so at the time of prescribing. You see, PBMs have Pharmacy and Therapeutics (P&T) committees that meet regularly to review literature and data and make determinations as to what drugs will be included in the formulary and any restrictions on the therapy. The P&T committee may have met – and changes been made – literally hours after the flat file was created. These updates would not be available to a prescriber until the next file has been created, processed and downloaded into the prescriber's EHR which can take, at a minimum, 14 days.

Second, because of the flat file process, the information must be presented at the plan or group level, not the individual patient level. How do we differentiate between plan-, group- and patient-level and why doges that matter? The best way to explain is in this manner: General Motors would be considered the "plan" to the insurance company, General Motors hourly employees in Bowling Green, Kentucky could be a "group" and Jane Smith would be an individual patient. Formulary and benefit information could vary by each level. For example, at the plan-level, certain drugs might not be covered but would be for hourly employees (negotiated by unions), creating discrepancies between the plan- and group-level. At the patient-level, Jane Smith could have burned through her deductible on a high-deductible health savings plan, and not be required to make co-payments at all.

Because of both F&B's flat file "snapshot in time" and "plan-group-patient level" situations, it is very difficult to give providers – to whom this is presented today – the patient's out-of-pocket cost information because there are many unknown factors such as pharmacy (in-network or out), site of service, etc. The best that insurance companies have been able to do is provide co-payment information

[3] https://www.cms.gov/Medicare/E-Health/Eprescribing/index.html .
[4] https://healthit.ahrq.gov/sites/default/files/docs/page/eRxReport.pdf.
[5] 42 CFR Part 423 published in the Federal Register April 7, 2008.

at the plan- or group-level, an incomplete picture that can cause confusion and frustration at the pharmacy or infusion center, if the cost differs from what the patient has been told.

Further complicating matters is that the comprehensive set of F&B fields are often optional, meaning that the payer doesn't have to provide all the information. This is logical because payers may not have certain pieces of information. However, some payers choose to not provide some data elements, as well. For example, while we know that Medicare requires prior authorization (PA) flags (so we know it's possible), one study using EHR formulary data for 100,000 patients revealed that only 33% of formularies contained at least one drug with a PA flag.[6] Without the flag, the prescriber does not know that PA is required so does not take steps to prospectively process an electronic prior authorization request.

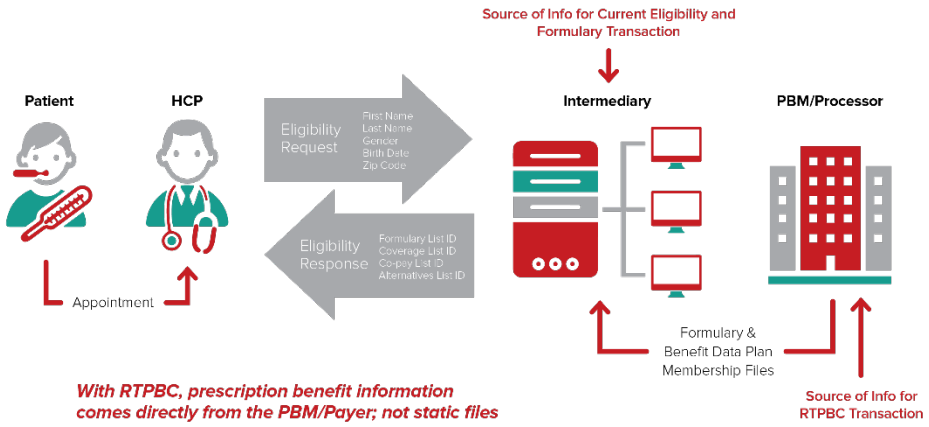
Finally, as previously mentioned, EHRs may lag in updating these files, so prescribers may not have the latest or most accurate information. Even if the file that was transmitted to Surescripts, aggregated and provided to the EHRs, at best, providers would only have access to the latest P&T committee findings.

It is these gaps that led to the creation of real-time pharmacy benefit check.

Benefits of RTPBC

In a nutshell, RTPBC delivers more accurate patient-level information about coverage and costs of drugs at the point of prescribing, to help doctors get their patients on therapy faster. Prescribers receive member price information (eg, member co-pay and cost sharing details), lower-cost therapeutic alternatives, coverage restrictions such as PA step therapy or quantity limits, channel options or the most cost-effective way for the patient to fill their prescription (ie, retail pharmacy, mail-order pharmacy, specialty pharmacy) and additional coverage and patient safety alerts.

The ability to access accurate coverage and drug cost information supports informed discussions between the prescriber and patient. This should lead to enhanced compliance with medication regimens, less prescription abandonment and fewer unnecessary office appointments, emergency department visits and hospitalizations. Prescribing the right drug for the right patient at the right time also leads to better health outcomes and improved medication adherence.



[6] AMA data presented at HIMSS19.

There is also value of RTPBC to payers. Last year, Point-of-Care Partners conducted research with executives of payers representing 95% of commercially covered lives, finding that these payers view RTPBC as a way to improve their basic, core performance indicators including drug utilization and costs; and administrative costs,[7] such as prior authorization.

Adoption of RTPBC

Since 2015, several vendors have developed RTPBC services. According to the most recent industry reports, 73% of the current EHR market, and 81% of the payer market, representing the majority of market share, have at least one of these RTPBC solutions integrated into their system.[8] Provider adoption of these services is also growing. According to the most recent report from Surescripts, as of December 2018, more than 100,000 prescribers are using their solution which translated into 6,300,000 transactions in the month of December.[9]

Finally, according to a recent report by CVS Health, prescribers using CVS Health's real-time benefits information are, on average, saving their patients $120-$130 per prescription by switching to a covered drug. According to the report, prescribers are switching to a covered drug 75% of the time, when the originally prescribed drug is not on the member's formulary. In situations where the original drug is covered, but a lower cost alternative is available, prescribers are switching patients to a clinically appropriate alternative 40% of the time, resulting in average out-of-pocket member savings of $130 per filled prescription.[10] Despite significant progress in adoption and impact, the industry still has a long way to go before we can realize the full potential of this transaction.

Shortfalls in Real-Time Pharmacy Benefit Check

The information currently provided in the RTPBC response from the PBM or payer to the physician has some inherent shortfalls. Today, the patient out-of-pocket cost data that is sent back to the physician only reflects the amount the patient will pay ***if*** they use their insurance coverage. In some cases, using insurance may not be the most cost-effective method for the patient. This is especially true for those who may have a high-deductible plan who have not yet met their annual deductible or for drugs that are offered by certain pharmacies at a lower cost than co-pay. In other situations, the drug may be covered under the patients' medical benefit as opposed to their pharmacy benefit. This is often the case for many of the high cost specialty medications. If a prescriber runs an RTPBC for a specialty medication, the prescriber may receive a message that the drug is not covered since RTPBC only checks the prescription coverage for a medication, not the medical benefit coverage.

---

[7] "Real-Time Pharmacy Benefit: The Payer Value Proposition", Point-of-Care-Partners, November 2018.

[8] https://www.covermymeds.com/main/insights/rtbc-scorecard/; accessed March 2018.

[9] https://surescripts.com/docs/default-source/intelligence-in-action/prescription-accuracy/2_2019-price-transparency-impact-report-data-brief.pdf; accessed March 2018.

[10] https://payorsolutions.cvshealth.com/insights/proven-savings-with-real-time-prescription-benefits; accessed March, 2018.

Second, one of the key aspects of RTPBC is the ability to provide an accurate out-of-pocket cost to the member. Unfortunately, the calculation of this amount is currently not consistent across each payer and PBM. In some cases, the PBM presents "patient pay amount" but does not always include deductible. In other cases, the patient out-of-pocket cost may be different for prescriptions filled with an in-network pharmacy vs. one out-of-network. If this information is not calculated into the response, what is displayed to the prescriber may not be accurate. Inaccuracies resulting from incomplete inputs could lead to similar frustration as the use of F&B files have caused. Patients want to be confident the out-of-pocket amount discussed with their doctor is what they can expect when they arrive at the pharmacy to fill their prescription.

Manufacturer discount programs such as patient co-pay assistance, manufacturer coupons or additional information around potential financial assistance through foundations and other organizations are other important payment factors. There has been industry discussion about whether access to these financial assistance programs may have unintended consequences. PBMs and payers believe these options may lead patients to start on a more expensive but less or equally efficacious medication. While drug manufacturers and other stakeholders continue to provide these options, which may be part of marketing efforts, but they do help lower the out of pocket cost of the medication for the patient. This "tug-of-war" between the PBMs and Manufacturers will likely continue.

Finally, there are several companies providing prescription discount cards and services for patients who pay cash for their prescriptions, but these services are, for the most part, available outside of the prescribing workflow and normally not accessed by the patient at the pharmacy counter after the prescription has been sent to the pharmacy.

Opportunities to Improve the Availability of Real-Time Pharmacy Benefit Check

Access to the RTPBC transaction is limited primarily to a prescriber's EHR. Today, for the most part, RTPBC is a transaction between a prescriber using their EHR and the PBM or payer. Some pharmacies and pharmacy systems are accessing this transaction with the payer, but there is little to no availability of RTPBC information direct to the patient. Some opportunities for improvement include:

Pharmacist Access to Real-Time Pharmacy Benefit Check. In October 2018, President Trump signed the "Know the Lowest Price Act" and the "Patients' Right to Know Drug Prices Act" into law, which removed the "gag clause" preventing pharmacists from consulting patients on lower cost medications. Although pharmacists can now have these consultations, most pharmacists do not have the tools to do so. Today, the transaction that informs the pharmacists in the pharmacy system is the NCPDP Telecommunications Standard. This standard is primarily used to adjudicate a pharmacy claim. This standard allows a pharmacist to determine if a medication is covered by the patient's prescription coverage; however, it does not return additional information on lower cost alternatives or a cash price for the patient. Implementation of RTPBC in pharmacy systems would allow pharmacists to have the tools needed to inform the patients of their options and help them navigate the prescription drug landscape.

Patient Access to Real-Time Pharmacy Benefit Check. Patients will also benefit from access to RTPBC data. While availability of RTPBC data directly to patients is limited, some PBMs and payers are giving patients access to this information through their portals. RTPBC data provided by PBMs usually does not

include availability of cost savings and/or cost reduction coupons or the cash price. Portals are not necessarily the most convenient way for patients to access the information that is available; an app a patient can open while at the pharmacy counter is a more likely scenario and more convenient for the patient. In order to improve the type of data available and methods of access to patients, Point-of-Care Partners recently began working with the CARIN alliance to develop a patient-facing RTPBC transaction.

The CARIN Alliance is a non-partisan, multi-sector alliance co-founded by former National Coordinators for Health IT, Dr. David Blumenthal and Dr. David Brailer; former White House Chief Technology Officer, Aneesh Chopra; and former Utah Governor, Secretary of Health and Human Services, Michael Leavitt. The Alliance comprises stakeholders representing all areas of the health care delivery system including government, providers, payers, health systems, consumers, patient advocates, EHR providers and third-party consumer solutions. CARIN's vision is to advance the ability for consumers and their authorized caregivers to easily get, use, and share their digital health information when, where, and how they want to achieve their goals.

As it relates to RTPBC, the alliance is promoting the ability for patients to access prescription drug information directly to help them navigate the prescription drug landscape. The alliance has recently put together a Real-Time Pharmacy Benefit Check Work Group (RTPBC WG) and is convening existing alliance members, such as payers, patient groups, and provider groups and additional health sector representatives such as manufacturers, PBMs, and pharmacies. The CARIN Alliance has asked us to participate as subject matter experts to provide input to the group to help identify data elements to be made available, the standards for digital health information exchange, and the scope of application for information to be shared.

Policy Considerations for RTPBC

Point-of-Care Partners supports public policy change as it relates to RTPBC to ensure completeness and accuracy of the information provided by the PBM or payer and the broad availability of the transaction to all stakeholders. The Notice of Proposed Rule Making released by CMS in November 2018 titled "Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses," (CMS-4180-P) could lead to the adoption of Real-Time Pharmacy Benefit Check beginning as early as January 1, 2020. The adoption by Medicare Part D will hasten adoption by other stakeholders. Point-of-Care Partners provided comments on the proposal,[11] some of which I will summarize now along with additional policy recommendations that should be considered by the committee.

As it relates to the CMS NPRM, we have provided the following commentary:

1. **Name of the transaction.** The proposed rule references a Real-Time Benefit Tool (RTBT). 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. 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

[11] https://www.pocp.com/wp-content/uploads/POCP_Comments_PartD-NPRM-re-RTPBC_December-2018.pdf.

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 or drugs covered under the patient's medical benefit. The industry is beginning work on what could be called a real-time medical benefit check (RTMBC).

2. **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. Point-of-Care Partners recommends a single standard be named because it will hasten adoption of the transaction and eliminate the potential for an unsustainable number of one-off solutions. If CMS decides to name a specific 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. Finally, if a specific standard is selected, CMS should require the development of a standard implementation guide to ensure consistent, industry-wide execution.

3. **Address the relationship with formulary and benefit files.** The proposed rule does not address the interaction between RTPBC and the formulary and benefit (F&B) standard. This is an important issue and needs to be clarified in the final rule. 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 adoption of RTPBC. Rather, F&B will evolve to support RTPBC by consistently alerting prescribers of the need to perform an 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, commercial payers have to populate the prior authorization field in the F&B file and make it available in the RTPBC response, and payers must address the gaps in F&B data. As a result, we recommend that CMS require payers to provide a minimum mandatory data set to populate F&B files as well as populate the prior authorization field in F&B files. Second, the final rule should specify that the RTPBC does not replace the eligibility-informed F&B check.

4. **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. We recommend that CMS 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.

5. **Integrate additional cost/access information.** Information gaps affecting patients' potential out-of-pocket liability exist today with real-time pharmacy benefit check. It begins with co-pay, which can vary by medication, patient and plan. In the proposed rule, CMS requires plans to share the negotiated price of a drug with the consumer. Point-of-Care Partners recommends that CMS require the inclusion of not only negotiated price in RTPBC, but a broader category of comparative pricing. Specifically, we believe prescribers and patients should have information that will help them determine whether they should obtain a prescribed drug under their

insurance benefit or under a possibly less expensive cash price. We also believe that under either of these scenarios, individuals should have access to pricing information for the pharmacies in their network that highlights where they can access the lowest negotiated price under insurance coverage or lowest cash price.

There is financial assistance offered by manufacturers, foundations, and states. For example, many manufacturers fund coupon and co-pay 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 co-pays 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. Having this kind of information in the real-time pharmacy benefit check can help the physician truly identify the most cost-effective options for their patients, ultimately improving outcomes and medication adherence and reducing costs.

6. **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 their family members' medication costs, alternatives, coverage restrictions, 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. Some payers currently provide patient-facing apps and portals today to allow patients to check the coverage and out-of-pocket cost of their medications, and there are patient-facing apps not affiliated with payers and PBMs to check the cash price for a medication, but there are few if any forums that have all the information in one convenient place. Patient access to cash drug price at their selected pharmacy is a required disclosure under recent "gag" clause changes. Some market-based tools even offer drug price cash comparison capabilities.

   From a policy perspective, we see several benefits of including comparative price information in real-time consumer drug price access tools. One benefit is to help ensure active compliance with gag clause requirements. Enabling patients to compare coverage prices vs. cash prices at multiple pharmacy locations will facilitate true comparison shopping and patient engagement in their health care costs.

   Stakeholders may also benefit from increased information sharing about fulfillment of prescriptions through cash pay transactions. Today, there is no mechanism for plans to record or track patient medication purchases made in cash. Closing this loop will contribute to better care coordination for the patient and can help plans as they strive to meet quality measures and improved outcomes.

7. **Erasing the "gag" rule culture.** Additional legislation should be passed to make RTPBC available for pharmacists. Great progress was made with the recent passage of the Patient Right to Know Drug Prices Act and the Know the Lowest Price Act of 2018 to remove the "gag order" clauses in contracts between pharmacies and payers or PBMs. But for a pharmacist to be able to proactively inform patients of the availability of a less costly drug or that cash payment is less than co-pay, pharmacists needs tools including RTPBC. RTPBC access for prescribers, patients and pharmacists will help create a new culture of transparency and open discussion.

Point-of-Care Partners, like CMS, ONC and many other key players in the industry, see the value in increasing drug price transparency, specifically through access to real-time pharmacy benefit check for prescribers, pharmacists and patients. The time and conditions are right to provide accurate, timely and patient-specific prescription drug coverage information as an enabler for stakeholders to choose the lower priced drug option, increased adherence and eventually improved patient outcomes.

Thank you for the opportunity to testify today. I would be happy to answer your questions.