D. Part D Explanation of Benefits (§ 423.128)

Section 1860D–4(a)(4)(A) of the Act requires Part D sponsors to furnish to each of their enrollees a written explanation of benefits (EOB) and, when the prescription drug benefits are provided, a notice of the benefits in relation to the initial coverage limit and the out-of-pocket threshold for the current year. We codified this EOB and notice requirement at § 423.128(e) by requiring the Part D EOB to include specific information written in a form easily understandable to enrollees. Part D sponsors must provide enrollees with an EOB no later than the end of the month following any month in which the enrollee utilized their prescription drug benefit.

Information about negotiated price changes for each of the prescription drugs covered for a beneficiary, including information about lower cost therapeutic alternatives, is not required to be in the EOB under the current regulation. Based on comments received, we are finalizing our proposal that sponsors must include negotiated price increases and lower cost therapeutic alternatives in their beneficiaries' Part D EOBs.

The Part D EOB is one of the principal documents that beneficiaries can rely on to understand where they are in the benefit phases and their changing outof-pocket costs throughout the year. This document is provided to beneficiaries every month for the immediately preceding month that the Part D benefit is used. As a retroactive monthly report, the EOB is the means by which beneficiaries can monitor their benefit utilization and prescription costs on a regular and frequent basis.

We received approximately 79 comments on this proposal. We have included a summary of the comments and our responses.

Comment: Commenters unanimously supported increasing drug pricing transparency for beneficiaries.

Response: We thank the commenters for their support. Lowering prescription drug costs is of critical and immediate concern to beneficiaries and the Administration.

Comment: Many commenters voiced concern that including drug pricing information on the EOB would be ineffective for the following reasons: (1) Its retroactive nature makes the price information not meaningful or actionable for the beneficiary; (2) its timing during a benefit year makes it not actionable by the beneficiary because of limitations on enrollment changes; (3) the nature of acute prescriptions means the information is not useful for shortterm medications; and (4) this information is not discernable without being read with the prescriber. While asserting different reasons, these commenters generally agreed that the drug cost information would not be meaningful, actionable or useful for the beneficiary due to the enumerated circumstances.

Response: Despite the EOB being a retroactive report, the information provided will allow beneficiaries to engage with their prescriber at their next point of care and discuss their choices in medication. This may lead to beneficiaries switching to a lower cost drug. Even if a beneficiary is not able to change plans mid-year based on the EOB information, the information may still be useful to the beneficiary in the situation we just described—to engage with their prescriber about their medication choices within their existing plan. To address the comments concerning acute prescriptions, we note that on the EOB as it is written today an acute prescription filled one time is not carried over on multiple EOBs. However, we believe there is no harm in including a negotiated price increase and a lower cost alternative for an acute prescription claim, when available. This additional information empowers the beneficiary and provides them with a holistic approach when reviewing their Part D benefit. We believe this, in turn, will ultimately spark dialogue between the beneficiary and their prescriber(s) about lower cost therapeutic alternatives in the future. Thus, we conclude that the EOB will empower the beneficiary with information about drug costs that the beneficiary does not currently have. This initiative will support CMS' commitment to promoting drug price transparency in the Medicare Part D program.

Comment: Many commenters suggested that drug pricing information will be more useful if provided through a prospective tool, such as a real-time benefit tool (RTBT) at the time of prescribing, rather than the EOB. They highlighted that beneficiary knowledge would be more accurate with real-time information on which decisions could be made with their prescriber at the point of care.

Response: Implementing a real-time benefit tool for beneficiaries is an effective way to provide beneficiary specific information about drug costs (for additional discussion about RTBTs, please see the previous section of this final rule). However, the EOB provides a different method of communicating drug pricing information directly to beneficiaries. Both are valuable price transparency tools.

Comment: Multiple commenters were concerned that displaying the percentage change in negotiated price would not be a helpful metric for beneficiaries when evaluating their Part D benefits. The commenters asserted that the negotiated price is not the correct price to display as it may not change throughout the benefit year, or if it does change, it may not impact the cost-sharing for the beneficiary. However, commenters did not provide alternative pricing that would be of greater impact to the beneficiary.

Response: We do not agree and believe providing this information to the beneficiary is valuable. The negotiated price information required to be included in the EOB is the percentage increase in the total cost for each prescription, when there is an increase, since the first claim of the current benefit year for each prescription drug claim in the EOB, which would display under each medication. Currently and under this new requirement, the EOB would still display the price paid by the beneficiary, plan and any other payer. While increases in negotiated prices may

or may not be directly proportionate to a change in a beneficiary's cost-sharing for a variety of reasons, we believe that ensuring beneficiary access to information about changes in drug pricing in the context of their specific use of the benefit will allow them to better assess the value they receive from their Part D benefit.

Comment: Multiple commenters pointed out the Part D EOB is meant to be a brief document but is lengthy and complex. As such, these commenters pointed out that including additional details would only make the document longer, thereby paradoxically making a beneficiary less inclined to read the document thoroughly. Therefore, our EOB proposal would defeat the intent of requiring additional information in it. Some commenters also mentioned that the EOB is not the appropriate document to disseminate the pricing information and will inevitably lead to increased beneficiary confusion. Commenters suggested improving the functionality of the Medicare Plan Finder and other beneficiary-facing tools to convey this information.

Response: We find the current structure of the EOB to be well-suited to include additional information on individual prescription drug claims. Other beneficiary materials are delivered on an annual basis, and are geared toward assisting Part D beneficiaries make enrollment decisions whether to remain with their current prescription drug plan or switch to another. By including these negotiated price increases and lower cost alternatives on a monthly basis in EOBs, beneficiaries will be in greater control of their prescription drug benefits and, with their prescribers, will be able to make more informed decisions about their care. Beneficiaries will have documented drug pricing information and will be able to seek assistance from their prescribers, pharmacists, SHIPs, and family members.

Comment: A few commenters believed that the proposed rule did not provide sufficient definition of a lower cost therapeutic alternative.

Response: The lower cost therapeutic alternatives will be determined by the sponsor based on its formulary, not by CMS. As such, any drug may be identified as a lower-cost therapeutic alternative for another drug if a Part D sponsor reasonably determines it to be so. As stated in the preamble of the proposed rule, lower-cost therapeutic alternatives (meaning drugs with lower cost-sharing or lower negotiated prices) will not be limited to therapeutically equivalent generic drugs if the original prescription fill is for a brand drug.

Comment: A few commenters wrote that the estimated implementation cost with respect to this proposal was understated in the proposed rule. These commenters also provided an estimate of their increased costs, citing that the programming would be more than CMS estimated, and also that these changes would contribute to increasing the length of the EOB document, thereby increasing printing and mailing costs for plans. Commenters did not provide alternative solutions for including the drug pricing information and/or lower cost therapeutic alternatives.

Response: We thank the commenters for providing us with their cost estimates. We have revised the estimated cost to implement the EOB updates; however, we still believe that these updates are necessary for adhering to the Administration's goal of drug price transparency and lowering beneficiary out-of-pocket costs. We will work with stakeholders to improve the model EOB to include this information in the most efficient and effective manner for beneficiaries and sponsors.

Comment: Many commenters wrote that amending the Part D EOB to include this information for the upcoming contract year, beginning January 1, 2020, was unreasonable and too burdensome.

Response: We thank the commenters for their concerns, and acknowledge that there will be administrative and programmatic costs to implement these changes. Given the level of effort involved in updating the Part D EOB, we are delaying the implementation date until January 1, 2021. However, given the potential benefits of these changes, we strongly encourage plans to begin implementing this requirement prior to January 1, 2021.

After consideration of comments received, we are finalizing the reassignment of paragraphs (e)(5) and (e)(6) of § 423.128(e) as paragraphs (e)(6) and (e)(7) to add a new paragraph (e)(5) that will require sponsors to include information about negotiated price increases, if any, and lower-cost therapeutic alternatives in the Part D EOBs. Based on comments received, as to information about negotiated drug price increases, we will require that Part D sponsors include the cumulative percentage increase, if any, in the negotiated price since the first claim of the current benefit year for each prescription drug claim in the EOB.

Second, CMS will require that Part D sponsors provide information about drugs that are therapeutic alternatives with lower cost-sharing, from the applicable approved plan formulary for each prescription drug claim, when such therapeutic alternative are available as determined by the plan. Also, the plan may include therapeutic alternatives with the same copayments if the negotiated price is lower.

Part D sponsors will be permitted and encouraged by CMS to take into consideration relevant beneficiary specific information, such as diagnosis, the indication for the prescription and completed step therapy or exception requests, when providing formulary therapeutic alternatives in the EOB that have lower cost-sharing. For example, if a plan is aware that a beneficiary has already fulfilled step therapy requirements and the beneficiary's physician has attested that the beneficiary is not able to tolerate a formulary alternative, that formulary alternative does not need to be included on the EOB for that beneficiary.

3. Adoption of a Real-Time Benefit Tool

As we explained in the proposed rule (83 FR 62152), the Medicare Part D program allows contracted entities that offer coverage through the program latitude to design plan benefits, provided these benefits comply with all relevant requirements. This flexibility results in variation in Part D plans' benefit design, cost-sharing amounts, utilization management tools (that is, prior authorization, quantity limits, and step therapy), and formularies (that is, covered drugs). We are aware of several Part D prescription drug plans that have begun to offer RTBT inquiry and response capabilities to some physicians to make beneficiary-specific drug coverage and cost data visible to prescribers who wish to use such data at the point-of-prescribing. We have reviewed multiple RTBT software solutions and have found that they are generally designed to provide patient specific clinically appropriate information on lower-cost alternative therapies through the prescribers' eRx or EHR systems, if available, under the beneficiary's prescription drug benefit plan. However, for those software solutions that are capable of providing such decision support, based on our current experience, we understand that the prescribers will only embrace the technology if the prescriber finds the information to be readily useful. Thus, we stated in the proposed rule that to ensure success, we believe that the Part D sponsor must present prescribers with formulary options that are all clinically appropriate and accurately reflect the costs of their patient's specific formulary and benefit options under their drug benefit plan. In addition, as stated in the proposed rule, those who use plans' current RTBT technology report that prescribers are most likely to use the information available through RTBT transactions if the information is integrated into the eRx workflow and electronic health record (EHR) system. This will allow the prescriber and patient, when appropriate, to choose among clinically acceptable alternatives while weighing coverage and costs. Since eRx is generally performed within the provider's EHR system, integration of the RTBT function within the EHR generally, and the eRx workflow specifically, appears to be critical for the successful implementation of the technology. However, we recognize that without an industry standard for RTBT, prescribers may be offered multiple technologies, which may overwhelm and create burden for EHR vendors. We also recognized that without a standard, the RTBT tool provided may not be integrated with a prescriber's EHR, thus limiting its utility.

As stated in the proposed rule (83 FR 62152), we are interested in fostering the use of these real-time solutions in the Part D program, given their potential to lower prescription drug spending and minimize beneficiary out-of-pocket costs. Not only can program spending and beneficiary out-of-pocket costs be reduced, but evidence suggests that reducing medication cost also yields benefits in patients' medication adherence. As mentioned in the proposed rule, a 2012 review of studies found that 85 percent of studies demonstrated that increasing patient cost-share for a medication was associated with a significant decrease in medication adherence.9 This review also revealed that 86 percent of these studies demonstrated that increased medication adherence was associated with improved clinical outcomes. With respect to studies that directly measured the impact of out-of-pocket costs on outcomes, 76 percent found that increased medication related outcomes such as additional medical costs, office visits, hospitalizations, and other adverse events. Subsequently published studies continue to reflect similar findings.

Therefore, we proposed that each Part D sponsor be required to implement one or more RTBT capable of integrating with at least one prescriber's eRx and EHR systems to provide complete, accurate, timely, clinically appropriate and patient-specific real-time formulary and benefit information to the prescriber. We also encouraged plans to use RTBTs to promote full drug cost transparency by showing each drug's full negotiated price (as defined in § 423.100), in addition to the beneficiary's out-of-pocket cost information.

We also stated that health care providers using the RTBT should ensure that individuals are aware that information about services or treatment, such as a future prescription, may be disclosed to the plan by the tool, and effectuate the individual's disclosure restriction request by refraining to use the tool in instances in which the patient intends to self-pay in full. We encouraged covered health care providers to discuss with the individual whether the individual desires the prescriber to use the RTBT as doing so will generally eliminate the beneficiary's ability to request disclosure restrictions as the plan will already be in possession of the query data regarding the desire to prescribe something for a specified condition.

We sought comments on our proposal, including the feasibility for plans to meet the proposed January 1, 2020 deadline, and how our proposal may or may not expedite our goal of giving each Part D enrollee and the clinicians who serve them access to meaningful decision support through RTBT. We also sought relevant feedback about RTBT standardization efforts; this includes the planned fulfillment of any milestones that standardization bodies have already met, or are likely to meet in advance of the proposed January 1, 2020 deadline. We noted that we would consider retraction of our rule if we received feedback indicating that it would be contrary to advancing RTBT within Part D, or if a standard has been voted upon by an accredited Standard Setting Organization or there were other indications that a standard would have been available before the proposed 2020 effective date. In such case, we indicated that we would review such standard, and if we find it suitable for the Part D program consider proposal of that standard as a requirement for implementation in our 2021 rulemaking, effective January 1, 2021. We also solicited comments regarding the impact of the proposal on plans and providers, including overall interoperability and the impact on medical record systems. Finally, we solicited comments regarding the impact of the proposed effective date on the industry and other interested stakeholders.

We received approximately 194 comments on this proposal. Following are summaries of the comments we received and responses to these comments.

Comment: Commenters expressed widespread conceptual support for our proposal as a way to accelerate use of electronic Real-time Benefit Tools (RTBT) in the Part D program. These commenters believed that the provision of patient-specific price and coverage transparency at the point of prescribing will enable patients and providers to make more informed decisions about medication therapy.

Response: We thank commenters for their support.

Comment: We received numerous comments relating to the proposed January 1, 2020 implementation date. Although several commenters stated that the 2020 deadline was achievable, the majority of comments expressed concern. Most commenters believed that it would be prudent to delay the implementation date until an industry standard was available with some commenters characterizing the proposed time frame as overly aggressive or unrealistic given the level of effort required to implement RTBT.

Response: These comments have persuaded us that implementing RTBT will take substantial effort and that a 2020 deadline may be too difficult to achieve for those plans that have not yet begun to implement a real time solution. Given the considerable level of effort involved in developing RTBT we are delaying the required implementation date until January 1, 2021. However, given the potential benefits of RTBT, we strongly encourage plans to facilitate earlier use of RTBT when possible and start implementing prior January 1, 2021.

Comment: Many commenters stated that requiring RTBT in absence of an industry standard will impede integration of real-time information into EHRs and eRx systems. Many commenters urged CMS to continue to work with the industry through the National Council for Prescription Drug Programs (NCPDP) to develop a national standard that could meet the Part D program's needs. A few commenters asked CMS to wait a year or two after a standard becomes available in order to give the industry time to implement it. They noted that the cost of integrating multiple RTBT systems into EHRs will be prohibitive and may be passed on to prescribers through fees to the providers. A commenter suggested that CMS require that RTBT be provided to prescribers free of charge.

Response: CMS continues to support interoperability as a way to reduce the burden on health care providers and, as noted in our proposed rule, we would have preferred to consider and name a single industry standard for use in Part D. However as an industry standard is not yet available and we wish to bring the benefits of RTBT to the Part D market as soon as feasible, we are finalizing the provision that each plan implement an RTBT of its choosing. Should a suitable RTBT standard emerge sometime in the future, we can consider it for future rulemaking. We also note that prescribers will be unlikely to use RTBT tools that impose a significant financial burden on their practices. We therefore encourage plans to work with those responsible for their real-time solutions to make sure that they present value to prescribers. The Department of Health and Human Services will continue to engage with standards development organizations, such as NCPDP to encourage the development of standards.

Comment: Several commenters cautioned that holding plan sponsors solely accountable for implementation of RTBT places an unfair burden on the plans and will not result in furthering CMS's goals of widespread use of the technology. Other commenters asked if a Part D sponsor would be considered compliant with this provision if their RTBT only integrates with one EHR.

Response: Though we believe that EHR and eRx providers will adopt welldeveloped RTBT solutions, we recognize that such acceptance is not always in the Part D plan's control. The proposed and final regulatory language make it clear that the Part D plan is responsible for supporting an RTBT capable of integrating with at least one EHR or eRX system, but stops short of placing the responsibility for widespread prescriber adoption on the plan. We are only requiring compatibility with at least one prescriber's eRx or EHR, since CMS realizes that without an industryadopted standard, it would be operationally unattainable for a plan to support an RTBT capable of integrating with all EHR or eRx systems that prescribers are potentially using. And, although Part D plans can make sure that the RTBT system is capable of integrating with an EHR or eRx system, the decision to integrate the RTBT with specific prescriber-facing systems is out of the plan's control. Since this rule addresses Part D requirements, we can only address the plan's readiness for integration at this point.

Comment: Some commenters sought guidance about what features and information would satisfy the requirement for a RTBT. Commenters suggested that RTBT include information on the drug that the physician intends on prescribing along with formulary alternatives; they asked if RTBT should include drugs' applicable cash price, beneficiary copayment, any drug utilization controls, or side effects of alternative therapies presented. Some commenters believe that presenting negotiated prices to the prescriber would provide value to the RTBT process, while most commenters believe that that information was either not relevant or was considered proprietary information that should not be widely shared. Some commenters believed that RTBT should include information with respect to all available pharmacy and delivery options while others believe that only the prices of alternatives available at member's selected pharmacy should be populated by the RTBT.

Response: Our proposed regulation indicated that the goal of RTBT is to provide decision support to prescribers by presenting them with relevant details about formulary information and alternatives to the drug which the provider intends on prescribing. Although we encourage the inclusion of the negotiated price in RTBT, we are not mandating it at this time as the majority of commenters opposed its inclusion stating that the information was proprietary and overly confusing. Provider groups opposed its inclusion, since it was outside the scope of their responsibility. However, we believe that RTBT must include some minimal data points that will enable a prescriber and patient to make informed medication choices at the point of prescribing. These include benefit information about the drug which the provider intends on prescribing, enrollee cost-sharing information, and comparable information on formulary alternatives (meaning those medications that may have a different copayment or coinsurance amount than the medication about to be prescribed but may have the same therapeutic efficacy). The benefit information should include patient-specific utilization requirements (such as prior authorization or step therapy requirements) that have yet to be satisfied at the time when the prescription is written, and copayment or coinsurance (or negotiated price values if included) at the patient's selected pharmacy.

Comment: Some commenters expressed concerns that the data populated in the RTBT would not be reliable, that the data would be inaccurate or that it would be used for purposes other than to provide decision support to the prescriber. Commenters stated that existing real-time solutions vary in their functionality and reliability. One provider group pointed out that prescribers are already seeing that some of the RTBT systems are not providing useful information. They report that these systems are causing more effort on the part of the prescriber without providing useful decision support. Other providers noted that the quality of the information provided by multiple vendors is variable, and suggested that CMS assess the outcomes of the alternative vendors.

Response: CMS expects that data presented through RTBT will be patient specific, timely, and accurate. Part D plans must make sure that they comply with these requirements. We are unsure what commercial purposes were of concern to commenters and how they would adversely impact the intended functionality. Should CMS become aware that RTBTs are being used in ways that are contrary to the Part D program goals, we will address the issues as they arise. Further, we believe that Part D plans are in the best position to assess the effectiveness of the RTBT solutions, since they have a financial stake in ensuring that their enrollees have access to the most cost-effective medications. We expect that widespread adoption of RTBT will, over time, facilitate improved functionality and administrative ease of using the tools in clinical practice. However, if such concerns are not mollified, we would expect that EHR vendors would offer feedback to the plans.

Comment: A few commenters suggested that we refer to RTBTs using other terms, such as real-time pharmacy benefit check or real-time pharmacy benefit transaction to more clearly describe our proposal. A commenter requested that we refer to the technology as a benefit check and not a tool.

Response: We understand that some terms may be clearer to certain readers. However, the ubiquity of the term RTBT leads us to believe that it is the correct term to use. In addition, the suggested terms were sufficiently close to our proposed term that we are convinced that RTBT is an accurate description of our regulatory requirement.

Comment: We received a number of comments objecting to our proposal that providers receive explicit patient consent before reviewing RTBT solutions. Commenters explained to us that requiring affirmative consent would result in providers having to modify their workflow and systems to capture such explicit consent. These systematic changes would require at least 18 months to adopt, implement, test, and remedy any issues. Educating providers across the country

on this requirement and implementing the system changes would take at least another three months, which calls into question the ability to fulfill this requirement prior to January 1, 2020. Though one commenter appreciated the proposed level of protection, all other commenters who addressed the issue stated that the proposed requirement would be a serious obstacle to the real-time process. For example, making system changes that normally require at least 18 months to make, within less than 6 months would require the hiring of significant amounts of new staff and put a burden on their systems to implement prior to the January 1, 2020 deadline.

Response: We are committed to ensuring that RTBT implementation happens as smoothly as possible. The RTBT regulation requires that each Part D plan implement one or more real-time benefit tools, but does not specify the circumstances under which a prescriber should use the technology. We expect that prescribers will only use RTBT when the information provided is useful. As the intent of the RTBT is to help the clinician know if a medication will be covered under a patient's prescription benefit coverage, we do not expect that prescribers will use the tool in those rare instances when a patient has expressed a desire to buy the medication outside of the insurance benefit. Yet, given the importance of protecting an individual from unauthorized disclosure of health information, we considered requiring patient consent before the RTBT was being used just to make sure that patients are fully cognizant that RTBT will be used.

However, on further reflection, under the current RTBT scheme, we believe that requiring that patients provide explicit affirmative consent before each use of an RTBT is unnecessary. In most instances, we expect that the choice about what prescription to prescribe will happen when a beneficiary is present, because the current ePrescribing standard requires the beneficiary to choose where the prescription is to be sent. This means they will be aware that their data will likely be transmitted to parties other than the prescriber. Furthermore, beneficiaries have the opportunity to ask their prescribers about what data is being sent over to the pharmacy.

We conducted more detailed research into how RTBTs would function in the Part D context, and we discovered that after the prescriber finishes consulting with the RTBT, they typically transmit the prescription to the pharmacy electronically. If the enrollee decides to private pay at a pharmacy, the pharmacy is required to send a failed claim notice if a beneficiary decides to pay for the prescription out of pocket, rather than all the information about the prescribed medication. This failed claim notice satisfies the § 423.120(c)(3) requirement for pharmacies to submit claims to the Part D sponsors or its intermediary whenever the Part D member ID card is presented or is on file at the pharmacy, which is a requirement without RTBT use. Thus, we encourage providers to discuss with the individual whether the individual desires to self pay as after the prescriber uses the RTBT the patient will no longer be able to withhold information about the prescription from their plan under 45 CFR 164.522(a)(1)((vi) (allowing the beneficiary to request disclosure restrictions if they pay for their prescription).

After reviewing the comments, we weighed these potential privacy concerns against the potential disruptions to effective adoption of RTBT raised by commenters. Especially since

pharmacy benefit information is generally already available to prescribers and pharmacies under typical patient interactions, we believe that RTBT use will fall within the category of health care treatment disclosures making the disclosure of health care data generally permissible without patient authorization. Nonetheless, we encourage prescribers to use RTBT judiciously and must always allow an individual enrolled in a Part D plan to instruct a prescriber not to use the system for any or all prescriptions, and prescribers should heed that instruction.

Comment: Several commenters suggested that CMS work with the Office of the National Coordinator for Health Information Technology (ONC) to develop incentives for integration of RTBT products into EHRs.

Response: CMS thanks the commenters for this suggestion. However, we do not believe that these incentives are required. Based on our research, we believe many EHRs are moving to integrate RTBTs into prescribers' works flows. In addition, since RTBTs are variable in their functionality it would be difficult for ONC to incentivize use of RTBT until an industry standard is implemented and tested.

Comment: A few commenters suggested that the F&B standards are no longer necessary and others asked us to clarify the role that the F&B standard should play in the future.

Response: In our proposed rule we clarified that F&B remains an important component of the Part D electronic prescription standard and plans must continue to support it. However, the future interaction between RTBT and the F&B standards are out of scope of this regulation.

Comment: A commenter requested that long-term care facilities be exempt from having to use a RTBT.

Response: CMS intends this regulatory requirement to apply solely to Part D plans. Although we encourage the use of RTBTs among providers, guidance for providers is outside of the scope of this final rule.

Comment: A few commenters suggested that CMS require Part D plans to develop a patient tool to provide prescription cost information to patients in addition to, or instead of, the prescriber facing tool we proposed.

Response: We appreciate the comments. However, our proposal was for a prescriber facing tool. A patient tool is outside the scope of this rule. We are finalizing the proposal for each Part D plan to implement an RTBT of its choosing, effective January 1, 2021. We strongly encourage plans to start implementing this provision prior to 2021. We are removing the proposed requirement that covered health care providers obtain explicit beneficiary consent prior to using the RTBT.

We are finalizing the proposal for each Part D plan to implement an RTBT of its choosing, effective January 1, 2021. We strongly encourage plans to start implementing this provision prior to 2021. We are removing the proposed requirement that covered health care providers obtain explicit beneficiary consent prior to using the RTBT