May 14, 2021

Mr. Jeff Grant
Acting Director
Center for Consumer Information and Insurance Oversight
Centers for Medicare & Medicaid Services
7501 Wisconsin Ave
Bethesda MD 20814

Dear Mr. Grant:

PCMA was pleased to discuss implementation of the Consolidated Appropriations Act (CAA) of 2021's surprise medical billing and transparency provisions with members of the Departments of Health and Human Services (HHS), Labor, and Treasury (hereafter "the Departments") on April 28, 2021. As a follow-up to this meeting, we are submitting these comments and requesting clarifications to better inform the Departments in advance of any rulemaking to implement these important provisions according to their statutory deadlines where feasible. We ask that you please share this feedback with members of the U.S. Departments of Labor and Treasury as appropriate as the HHS team works with them to craft regulations and guidance.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the exchanges established by the Affordable Care Act. Our members work closely with plans and issuers to secure lower costs for prescription drugs and achieve better health outcomes.

PCMA supports the Administration's desire to bring meaningful and actionable transparency to health care purchasers and consumers. Already, PBMs are at the forefront of health care price transparency. Currently, PBMs inform enrollees about their coverage for specific drugs, which pharmacies are available in their plan's network, and their expected out-of-pocket (OOP) costs for their prescriptions, often through online tools. PBMs also provide real-time information to prescribers at the point of care, including utilization management requirements (e.g., prior authorization and step therapy) and lower-cost therapeutic options available in the plan's formulary. They have also created systems through which prior authorization requests can be resolved electronically, which streamlines enrollee access to prescription drugs.[1] We stand in support of consumer-facing transparency that helps consumers and their health care providers make the best decisions for their care.

[1] 85 Fed. Reg. 86824, December 31, 2020.

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We begin by seeking confirmation that pharmacy services are not included for the purposes of implementing the surprise billing provisions of the No Surprises Act (specifically, Sections 107, 114, and 116, of Division BB, Title I of the CAA), followed by specific questions and recommended approaches for the Departments should pharmacy services be included. We then discuss Division BB, Title II (Transparency)'s Section 204, which is specific to prescription drug price transparency, and specific recommendations for implementation. We close with a discussion of the Department's procedural approach to implementation of these provisions.

I. Legislative Intent Regarding Pharmacies and Pharmacy Services in the Surprise Billing Provisions of the No Surprises Act

As a threshold matter, group health plans, health insurance issuers, and their contracted PBMs need to know if the Departments intend to apply the surprise medical billing provisions of Title I of the No Surprises Act to pharmacy providers and pharmacy services including prescription drugs.

One could argue that since the situation addressed by the law is specific to medical providers and facilities, and not pharmacies and prescription drugs, that the law should be read to exclude pharmacies and pharmacy services. Specifically, the Title I provisions (sections numbered 101 to 118) are all an integral part of the No Surprises Act, and in furtherance of its purpose to prevent surprise medical bills. Each provision is integral to prevent surprise billing by requiring that (1) mechanisms be in place to ensure that members have up-to-date information on in-network and out-of-network providers (section 116), and (2) mechanisms are in place to ensure members know what they will owe when they use in-network v. out-of-network providers (sections 107 and 114). There is thus a clear argument that the Title I provisions are therefore of limited to the providers and benefits governed by the surprise billing processes and protections. An argument for exclusion also exists by reading the Division, BB Title II "Transparency" provisions. The Title I provisions use terminology usually reserved for medical providers and services rather than pharmacy services (e.g., "Items and services" instead of "prescription drugs" as used in Section 204, "provider" instead of "pharmacy", a requirement to include a provider's "specialty" in the directory, and "furnishing" rather than "dispensing").

That said, and as we discussed during the April 28 meeting, PCMA support improvements to consumer-facing health care price transparency including in the pharmacy benefits space. Deductible and out-of-pocket limits apply to pharmacy services. Prescriptions are dispensed at out-of-network pharmacies. Price comparison tools would seem incomplete without prescription drugs. Outside of No Surprises Act provisions, insurer requirements under the Public Health Services Act do not exclude pharmacy services. Thus, in the event that any or all of these sections apply to pharmacy benefits, the tables below lay out the questions our members will need answered.

A. Section 107, Transparency Regarding In-Network and Out-of-Network Deductibles and Out-of-Pocket Limitations, January 1, 2022

Section 107 requires group health plans and health insurance issuers to provide insurance cards that clearly disclose and provide the enrollee the amount of the in-network and out-of-network deductibles and the in-network and out-of-network out-of-pocket maximum limitations for medical care. Clear and concise enrollee materials are an important tool to communicate expectations under the law.

Table 1. Section 107 Questions and Suggested Responses

Question	PCMA Suggested Answer
Is rulemaking alone sufficient or will sub-regulatory guidance also be required?	Based upon the language in the enacted statute and the level of detail to address logistics and timing for updating cards, especially when they are physical cards that need to be printed and mailed, we believe rulemaking and subregulatory guidance (e.g. a formal PRA process) is needed.
Do the Departments need to further define "physical" or "electronic" insurance identification card for purposes of providing deductible and out-of-pocket limitations?	No. It is clear to our membership that "physical" indicates printed cards and "electronic" is the parallel available online or on a mobile application. We would note that the physical card is distributed prior to the start of the plan year and typically not re-issued. Changes to an electronic card conveying this information would similarly be rare.
How do the Departments wish to differentiate between pharmacy and medical benefit?	Health plans may either provide two separate cards or use one card for both pharmacy and medical benefits. If using one card for both pharmacy and medical benefits, the Departments will need to consider the amount of detail that any physical card can fit. It is easier to provide this information on a website or by phone versus a physical card. The insurance card should provide just the required dollar amounts on in-network and out-of-network deductibles and the in-network and out-of-network out-of-pocket maximum limitations and direct the enrollee to see more details online or through the call center. Further, in 2023, PBMs and issuers will need to re-card again due to BIN expansion requirements (6- to 8-character change). Re-carding for both efforts seems excessive and extremely costly for little value. The Departments should consider pushing this requirement by a year to coincide with BIN expansion.
How do the Departments wish to address plan designs where the deductible and out-of-pocket limitations differ between the pharmacy and medical benefits?	Health plans will also have to provide beneficiaries with information that separates in-network and out-of-network deductibles and the in-network and out-of-network out-of-pocket maximum limitations for medical versus pharmacy benefits. However, a physical card may not have enough space for this, as noted above. Information on limits for drugs covered under pharmacy versus medical benefits will need to be provided online as well or available via a call center. Our PBM

Table 1. Section 107 Questions and Suggested Responses

Question	PCMA Suggested Answer
	members recommend that the Departments grant issuers and PBMs flexibility in determining how best to convey this information.
How do the Departments wish to address the requirement of a single telephone number/website for consumer assistance when many plans have separate contact information for medical benefit and pharmacy benefits? (And other benefits.)	The statute requires that a single telephone number or website be available for consumer assistance. However, this is not possible since separate contact information is required when medical and pharmacy benefits are separated. In these quite common carve-out plan arrangements, the medical vendors and PBM do not interact except to exchange cost-sharing accumulator data if the deductibles are combined and for annual out-of-pocket limits. Having a single telephone number and website would be challenging due to the volume of websites and phone numbers that will need to be managed due to the numerous clients and medical vendors impacted. The industry standard card allows for the appropriate phone numbers for the members, pharmacies, and providers to call. Changing this process will introduce an additional level of complexity that will result in more member confusion and will not provide a simple result/outcome. We recommend that the Departments grant issuers and PBMs greater flexibility to list multiple phone numbers for each benefit segment. In addition, behavioral health and imaging are other service lines often administered by an entity other than the issuer. Clear instructions on which number to call will best triage the enrollees' needs.
PCMA Recommendation: The Departments should issue rulemaking and subregulatory guidance to address situations where more than one card is issued and provide clarity to plans.	

B. Section 114, Maintenance of Price Comparison Tool, January 1, 2022

This section of the CAA requires group health plans and issuers, including those health plans unchanged since the enactment of the ACA,[2] to provide an online price comparison tool that returns the enrollee's coverage and cost-sharing requirements and make such information available by telephone to enrollees by January 1, 2022. In many ways, this provision mirrors the Transparency in Coverage final rule.[3] The few differences between Section 114 and the final rule include that the final rule requires the information be made available online and in print

[2] We are henceforth referring to these plans, defined at Section 1251 of the Patient Protection and Affordable Care Act of 2020, in this way rather than the term used in the statute. The term used in the statute has a history embedded in the enslavement of Black persons in the U.S.
[3] 85 Fed. Reg. 72158, November 12, 2020.

rather than by telephone, and is not required until 2023 for the first set of 500 shoppable services and 2024 for all covered items and services.

In response to the Transparency in Coverage proposed rule, PCMA commented in support of such consumer-facing efforts as price transparency.[4] Tools that allow enrollees and their health care providers to make the most informed decisions improve the efficiency of health care delivery. We commented that nearly all plans and issuers offer such tools today, and that one way to reduce the administrative burden on plans to comply with the rule would be to "deem" existing tools as sufficient if they meet a minimum set of standards, while the Departments worked out more technical updates for later years. The final rule did not accept existing tools, but instead provided more time for plans to comply.[5] Given the much more accelerated timeline imposed by the new law, we recommend the Departments again consider accepting existing tools as sufficient at least for an interim period while further standards are developed. Existing tools will still provide important transparency for enrollees and avoid delays in getting them useful information. Below we provide additional questions and suggested answers on the implementation of this provision.

Table 2. Section 114 Questions and Suggested Responses

Question	PCMA Suggested Response
Is rulemaking required?	Not necessarily. The Departments could provide a statement or advisory opinion spelling out that existing tools that provide enrollees specific cost sharing based on a selected service at a selected provider meet the legislative requirements. However, should the Departments disagree and determine that existing tools cannot be compliant *prima facie* then full notice-and-comment rulemaking would be required to develop industry-wide standards.
What are the features of existing price comparison tools?	Most existing tools in the marketplace allow an enrollee to find coverage, price, and cost-sharing information for a select set of services. Specific to prescription drugs, one such issuer's drug pricing tool allowed us to: • Price a new drug (not yet prescribed) or look at prices for previously filled prescriptions; • Search by generic or brand name; • Select a specific dosage, if known, or default to the most common dosage; and • View the lowest-cost mail-order and retail pharmacy prices available.

[4] PCMA filed comments on Transparency in Coverage (January 29, 2020)

[5] Nonetheless, to give plans and issuers additional time to prepare, the disclosure requirements related to cost-sharing liability estimates in the final rules are not applicable until plan years (or in the individual market, policy years) beginning on or after January 1, 2023, providing two years for implementation, which should give plans and issuers sufficient time to ensure that they are able to comply. (85 Fed. Reg. at 72194)

Table 2. Section 114 Questions and Suggested Responses

Question	PCMA Suggested Response
	In our view, existing tools that meet the statute's plain language should satisfy the requirements.
Would separate tools offered by the plan for medical services and its contracted PBM for pharmacy benefits be acceptable?	We recommend that the Departments allow issuers to designate such a tool to satisfy the provision of cost-sharing information for pharmacy services. Issuers and self-funded group health plan sponsors may have no experience in pharmacy benefit administration, and significant IT investments have been made by contracted PBMs to create many of these tools already.
PCMA Recommendation: The Departments should issue guidance deeming existing tools offered by issuers (and contracted PBMs) sufficient so long as they meet the requirements described in the law for 2022.	

C. Section 116, Protecting Patients and Improving the Accuracy of Provider Directory Information, January 1, 2022

Section 116 requires group health plans and health insurance issuers to have up-to-date directories of their in-network providers. They are also required to promptly remove providers who are no longer in-network. This directory information must be available to patients online or provided to them within one business day of an inquiry. Furthermore, if a patient provides documentation that they received incorrect information about a provider's network status prior to a visit, the patient will only be responsible for the in-network cost-sharing amount.

Table 3. Section 116 Questions and Suggested Responses

Question	PCMA Suggested Answer
Does this provision apply to pharmacy networks?	We discussed at the outset of this section that we need the Departments to promptly confirm the exclusion of pharmacy services. With that in mind, we wish to describe pharmacy networks in more detail for the Departments. In general, pharmacy networks are large and inclusive, and pharmacy search tools available to members through the member portals are updated frequently based on NCPDP information. Print directories for pharmacy networks would be voluminous and costly and would become obsolete almost immediately. Additionally, plans that manage medical benefits separately from pharmacy benefits may have managed networks or custom networks that include an in-house pharmacy, so there may effectively be many different networks managed by each PBM on behalf of their clients. The Departments should consider deeming member portal tools and telephone access to information about

Table 3. Section 116 Questions and Suggested Responses

Question	PCMA Suggested Answer
	pharmacy networks to be compliant as long as the information is updated in accordance with the statutory timeframes.
Is rulemaking or subregulatory guidance required?	Based upon the language in the enacted statute and the existing NCPDP procedures external to the Departments already in place to maintain up-to-date verified pharmacy network directories, subregulatory guidance (followed by rulemaking to formalize such guidance) is requested that clarifies the following: ▪ Plans should update print directories no more than frequently than every 6 months and web-based directories no more frequently than every 90 days. ▪ The requirement of removal of providers within 2 business days should apply only to the web-based directories.
Should plans provide a separate process through the PBM for verifying pharmacy participation for this requirement?	Yes. In the event that this provision is applied to pharmacy benefits, the Departments should allow issuers to delegate this function to their contracted or aligned PBM. Beyond the two-business day requirement, the 90-day audit process envisioned by the statute is also not necessary in the pharmacy world. PBMs rely on NCPDP information (updated weekly). Contractually, pharmacies must keep that information current. We'd ask that this type of ongoing maintenance process would meet overall intent
How would providers removed from a network mid-plan year be treated for purposes of member reimbursement requirements?	Pharmacy networks are generally wide and inclusive, rather than narrow and exclusive. PBMs tend to manage networks to expedite access and incentivize pharmacies through bonuses and price concessions to meet quality metrics that are often tied to quality measurement ratings. Pharmacies are removed from networks when they fail to meet those metrics or are under a credible allegation of fraud, waste, and abuse, for example. Given this, we recommend that claims from pharmacy providers removed from a network midyear not be subject to the difference in the out-of-pocket cost provision except upon appeal by the enrollee.
PCMA Recommendation: The Departments should issue guidance clarifying the differences between medical provider and pharmacy network obligations, followed by rulemaking to formalize the guidance.	

II. Implementation of Section 204, Reporting on Pharmacy Benefits and Drug Costs

Under this section of the CAA, group health plans and health insurance issuers are to report to the secretaries of the Departments the following information:

- The top 50 drugs by total volume, spending, and annual spending growth for the previous plan year.
- Total spending and enrollee out-of-pocket spending for select categories of health care services including prescription drugs for the previous plan year.
- The amounts paid for each therapeutic class of drugs covered by the plan.
- The amount of rebates collected from drug manufacturers for the 25 most-highly rebated drugs and the contribution of those rebates to enrollee cost sharing or health insurance premium reduction including attributing shares to employers and employees where applicable.

The first disclosure is due one year after enactment (December 27, 2021) with reports following on June 1 of each year thereafter. Eighteen months after the first required disclosure deadline, and biannually thereafter, the Departments will publish reports aggregating these data.

PCMA shares the drafters' goals of better understanding the role of prescription drug prices and rebates on total spending. Below we lay out a series of questions and suggested responses for the Departments prior to finalizing any regulation and subsequent data collection forms through the PRA process. We also note that in order to report some of this information, contracts between PBMs and their client plans and issuers may need to change, necessitating additional time between finalizing any data collection procedures and actually collecting these data.

Plans are experiencing a substantial increased administrative workload due to several reporting initiatives at both the federal and state level. While we support price transparency and real-time benefit tools for patients and providers, as the Departments consider the regulations and subsequent technical specifications for the CAA, we emphasize the importance of uniformity in reporting requirements and consistency in data elements between Section 204 and the Transparency in Coverage final rule to reduce the operational burden on plans.

Table 4. Section 204 Questions and Suggested Responses

Question	PCMA Suggested Response
Is rulemaking required?	Based upon the language in the enacted statute and the level of detail that is needed to fulfill the disclosure obligations, rulemaking will be required. These rules should align definitions in the statute to those existing in other reporting programs under the Departments' authority. Following an initial round of rulemaking, annual guidance authorized under the rulemaking for non-material changes, with an opportunity to comment, would be sufficient rather than full annual rulemaking.
When should reporting begin?	Reporting should not begin until at least six months after all final guidance is published for this provision (meaning the culmination of any required PRA process). Regulated entities are entitled to advance notice of the exact contents of the data they are required to disclose and to have sufficient time to build the systems necessary to do so. Our PBM members rightly hesitate to build out IT systems "at risk" based on

Table 4. Section 204 Questions and Suggested Responses

Question	PCMA Suggested Response
	an enacted law, let alone a proposed rule or early round of information collection forms.
At what level should the reporting occur?	While the statute says: "a group health plan or health insurance issuer," the Departments should collect the least granular level of detail that would be reasonable. (In terms of QHPs, this would be HIOS-7 which would identify the issuer plus the state. Similar identifiers would need to be developed for use beyond QHPs.)
For what time period should initial and subsequent reporting occur?	The statute requires the "previous plan year" for both the initial reporting due December 27, 2021 and subsequent annual reporting due June 1. **We do not believe the Departments can create data collection forms in time for the December reporting and should delay initial reporting to the June 1, 2022 statutory deadline.** Even for June 1, 2022, PBMs on behalf of their clients need a sufficient amount of time to "close out" the prior plan year. June 1 may not be enough time to close out a 2021 plan year that ends of December 31, 2021. We recommend at least six months, rather than the five months this would provide. We also suggest the Departments collect data on a calendar year basis for simplicity of their own eventual reporting. If the Departments feel compelled to retain the June 1 reporting deadline, we suggest the Departments collect information as follows: • Initial reporting, due by June 1, 2022 (and each June 1 thereafter), for calendar years ending December 31, 2020 (and December 31 of each preceding year thereafter). However, should the Departments feel they have flexibility to move the June 1 date back to accommodate plan year close-outs, they could collect *more recent* data sooner. • Initial reporting, due by **August 1,** 2022 (and each August 1 thereafter), for calendar years ending December 31, **2021** (and December 31 of each year thereafter). These periods will allow plenty of time from the close of a plan year to account for claims reversals and reconciliations. Calendar year reporting is also more meaningful (and less burdensome) should reporting occur at the group health plan or issuer level. Further, as noted above, we believe the Departments should implement a six-month implementation schedule. The proposed timeline above (June 1, 2022 = data through December 31, 2020, or August 1, 2022 = data through December 31, 2021) allows for both claims reconciliation

Table 4. Section 204 Questions and Suggested Responses

Question	PCMA Suggested Response
	and for IT systems build-outs for the initial reporting. These timelines can run concurrently.
How do the Departments wish to define a drug, in order to measure by volume and spending?	For these data to be most meaningful, the Departments should not collect data at the NDC level, but less granularly, at the drug name or trade name level.[6] For reporting by volume, the Departments would benefit from knowing which ingredients form the most commonly dispensed drugs, rather than which of a specific manufacturer's dosage form, strength, and quantity is most often dispensed. Similarly, for spending and price changes, it would be important for the Departments to know the costliest drug names or trade names rather than the specific NDC dispensed. Manufacturers often market multiple dosages, forms, and strengths which may otherwise not reveal total spending unless combined at the drug name level.
How do the Departments wish to measure total spending growth?	The statute would seem to require that plans and issuers report the 50 drugs with the largest year-over-year spending growth. This could be intended to capture "watch outs" in therapeutic classes with rising costs. However, as written in the statute, the Departments are likely to capture many drugs with large increases in utilization from the prior year, rather than those with price increases. We believe a more meaningful measure of prescription drug pricing dynamics would be the 50 drugs with the largest year-over-year spending growth *that is driven by manufacturer price increases*. This calculation could be made at the drug name or trade name level by comparing prior year units and unit prices to current year values.
How do the Departments wish for plans and issuers to capture physician-administered drugs?	New sub paragraph 2799A–10(a)(7)(a) requests spending across three categories and an "other." We recommend the Departments provide guidance that the costs associated with drugs administered in hospitals, by primary care or specialty care providers or as part of other medical costs be included within those categories and not within the prescription drug category. For the most part, cost and access to these drugs is not managed in the same way that retail and mail-order prescription drugs are managed, and in relation to new subparagraphs (8), (9), and (10), the Departments should compare "apples to apples."
How should premium payments be allocated?	A plan or issuer may not know the actual allocation of premium payments by the employer or its employees. Clients may not want to disclose this to their issuers. As noted above, client-level reporting may be more practicable, though multiple reporters (clients for some fields,

[6] For information about Medi-Span's Generic Product Identification classification system see https://www.wolterskluwer.com/en/solutions/medi-span/about/gpi.

Table 4. Section 204 Questions and Suggested Responses

Question	PCMA Suggested Response
	plans and issuers for others) could make data collection, aggregation, and analysis difficult for the Departments.
How should the Departments define "therapeutic class" under subparagraph (9)(A)?	We recommend the Departments adhere to a single industry standard. There are several in use today, each being proprietary to their owners and the PBMs that subscribe to them. See MediSpan,[7] First Databank,[8] USP,[9] AHFS,[10] and ATC,[11] for example.
How should PBMs identify the 25 most highly-rebated drugs?	We recommend the Departments rely upon the same definitions as above – total rebates and remuneration paid by GPI-10 or drug name.
Should the Departments spell out a rebate allocation methodology?	Rebates may need to be allocated across plans within a given PBM, across clients within an issuer/PBM, and across drugs within a PBM. All three instances represent methodological challenges. Reconciliation rules already exist and thus we recommend the Departments confirm that any reasonable allocation methodology is acceptable. For example, those used in the Medicare Part D program.
Should reporting requirements differ depending whether the PBM is aligned with the plan or issuer (owned or owns it) or contracted to the plan or issuer?	No. Creating separate reporting streams yields not additional detail or value for the Departments.
Through what platform should data be reported?	To simplify the administration of this reporting program, the Departments could consider having all reporting move through HIOS. HHS would need to grant access to Labor and Treasury. From a reporting standpoint, depending on other choices made, HHS would need to grant access to employers as well. We believe a single platform for all reporting by all entities will be simpler to stand up and administer than multiple programs.
Should any rebates passed through directly to enrollees at the point of sale be excluded from "rebates and other remuneration"?	No. Rebates and other remuneration should not include amounts received by enrollees from manufacturers. The statute is clear that this term only includes amounts received by plans and their service providers. To the extent that a PBM administers a point-of-sale rebate program for their client (in whole or in part), these should be reflected as rebates received by the plan and then passed on to the enrollee, etc. negotiated by the PBM..

[7] See https://www.wolterskluwer.com/en/solutions/medi-span/about/gpi
[8] See https://www.fdbhealth.com/applications/drug-formulary-management
[9] See https://www.fda.gov/regulatory-information/fdaaa-implementation-chart/usp-therapeutic-categories-model-guidelines
[10] See https://www.ashp.org/Products-and-Services/Database-Licensing-and-Integration/AHFS-Therapeutic-Classification?loginreturnUrl=SSOCheckOnly
[11] See https://www.who.int/tools/atc-ddd-toolkit/atc-classification

Table 4. Section 204 Questions and Suggested Responses

Question	PCMA Suggested Response
	However, to the extent that the Departments are envisioning the reporting of manufacturer direct financial assistance, those payments certainly should be excluded.
PCMA Recommendation: The Departments should issue rulemaking to define a number of critical terms so that PBMs on behalf of issuers can report useful information accurately. The reports the Departments will generate can serve to highlight important trends in manufacturer prescription drug pricing behavior.	

III. The Departments Should Follow a Transparent Procedure Despite the Tight Implementation Schedule

Adherence to transparent policymaking procedures such as a robust public comment process and well-developed timelines is necessary for successful implementation of laws and trust between the regulated public and federal agencies. However, while the CAA has some impending effective dates that will make following this process and meeting the statutory deadlines challenge, PCMA nevertheless urges the Departments to proceed with the standard rulemaking process and, where necessary, exercise enforcement discretion if this means that the statutory deadline will not be met.. Our experience suggests that following the rulemaking process yields a better compliance outcome. PCMA understands that the No Surprises Act contains numerous provisions with impending effective dates that make full notice-and-comment rulemaking and subsequent subregulatory processes challenging. We believe the public's need to inform the process outweighs the regulators' need to meet statutory deadlines.

Many of the CAA provisions discussed in this letter may require the Departments to undertake full notice-and-comment rulemaking, consistent with the statutory language where applicable and informal rulemaking standards under the Administrative Procedures Act, as well as compliance with relevant Paperwork Reduction Act approval processes. In many provisions, the statutory language on its own provides inadequate detail for implementation. Therefore, agency level regulation and sub-regulatory guidance will be necessary. Any agency action will be one from which "legal consequences flow."[12]

We caution the Departments to not err on the side of statutory deadline compliance but instead on the side of public involvement. The Departments should not forego the usual rulemaking process and has no good cause to do so simply because it expects to run out of time. The law's deadlines alone do not justify forgoing an opportunity for meaningful public comment. While there may be instances where "good cause" counsels in favor of an expedited pathway,

[12] *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997).

including through interim final rulemaking, such exceptions should be strictly limited to instances in which notice-and-comment rulemaking is truly unnecessary or impracticable. For these provisions, good cause is neither practical nor appropriate.

Even if rulemaking is expedited, there may be instances where the required rulemaking, public comment processes, and other regulatory approvals (as well as implementation windows) do not allow for implementation by the statutory effective dates. We encourage the Departments to seriously consider exercising enforcement discretion (and communicating so with sufficient notice and clarity) where it is clear deadlines will not be met. This will be particularly important to consider when evaluating processes and investments that regulated entities will need to make to be compliant with the law. If the rules and guidance won't be out in time to meet the statutory deadlines, the Departments should exercise enforcement discretion until regulated entities have been given sufficient time to implement following final rulemaking and guidance.

Conclusion

We thank the Departments for the opportunity to provide comments on the implementation of this important legislation. PBMs support the Administration's efforts to provide meaningful price and cost-sharing information to enrollees and purchasers. If you need additional information, please contact me at tdube@pcmanet.org.

Sincerely,

Timthy Dube

Tim Dube
Vice President, Regulatory Affairs

cc: Kristin Bass, Chief External Affairs Office, PCMA
Amber Rivers, Employee Benefits and Security Administration, Department of Labor
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