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Submitted electronically via: http://www.regulations.gov

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10715/ OMB Control Number 0938–1372
Room C4–26– 05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Re: Transparency in Coverage Information Collection Request (CMS-10715)

To Whom It May Concern:

On behalf of America's Health Insurance Plans (AHIP), we are writing to submit comments in response to the Centers for Medicare and Medicaid (CMS) Transparency in Coverage information collection request (ICR) under the Paperwork Reduction Act (PRA), published in the *Federal Register* on December 30, 2020.[1] The ICR and related detailed PRA materials (CMS-10715) propose model notices and data elements related to implementation of requirements under the Transparency in Coverage final rule.[2]

AHIP is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. Americans deserve access to comprehensive, quality, affordable coverage. AHIP is committed to advancing policy solutions in support of these goals.

AHIP's member health insurance providers are committed to empowering consumers with meaningful, easy-to-understand information and tools to help them make better informed health care decisions for themselves and their families. Our focus is on solutions that give consumers data that is personalized and actionable, preserves patient privacy, and does not undermine competition. With this in mind, we continue to have significant concerns with the requirement for public disclosure of negotiated rates. Third party app developers, the intended audience for machine readable files, would not have access to an individual enrollee's policy, plan benefits, and real-time accumulators, which would prevent such apps from providing personalized and accurate cost estimates.

Our comments address the following issues:

- *Implementation Timelines*. Pause implementation of the Transparency in Coverage Final Rule to evaluate and align overlap with transparency requirements under the Consolidated Appropriations Act of 2021, enacted in late December 27, 2020, in Title I of Division BB ("No Surprises Act").

- *Ensuring Consumers Benefit.* Focus transparency requirements on disclosing health care cost information in a manner that directly supports consumer decision-making.

[1] 85 FR 86567, December 30, 2020
[2] 85 FR 72158, November 12, 2020

- *Technical Comments on Machine-Readable File Requirements.* Address foundational concerns with technical aspects of the proposed machine-readable files.

Implementation Timelines

We recommend CMS pause implementation of the Transparency in Coverage final rule. The rule was finalized before enactment of the No Surprises Act, resulting in several overlapping and sometimes conflicting requirements around cost calculators, advance cost-estimates, and prescription drug data. The Administration should pause implementation of the final rule while assessing this overlap and updating rulemaking to ensure a cohesive set of policies that support consumer access to meaningful cost information. CMS should issue new notice and comment rulemaking to reconsider the machine-readable file requirements and better align them with other transparency tools and new requirements in the provisions under the No Surprises Act.

CMS should seek stakeholder input on the requirement for historical net prices. The requirement to report information on historical net prices was not included in the proposed rule. AHIP has significant concerns that disclosure of historical net prices would not provide useful information on out-of-pocket costs to consumers and would result in increases to drug costs. Further, Sec. 204 of Title II of the No Surprises Act requires similar prescription drug pricing information be reported to the Departments of HHS, Labor, and Treasury. This new statutory requirement is intended to achieve similar objectives with respect to reporting prescription drug cost information but does so in a more focused, thoughtful manner. Sec. 204 explicitly states no confidential or trade secret information shall be provided in order to prevent adverse consequences for competition. We strongly recommend CMS not proceed with requiring disclosure of historical net prices through the Transparency in Coverage Final Rule and this ICR. At minimum, CMS should seek stakeholder input on historical net prices through notice and comment rulemaking and align prescription drug reporting requirements to avoid duplication and ensure neither data reported to the Secretaries nor disclosed to the public discloses confidential or trade secret information.

Ensuring Consumers Benefit

CMS should ensure transparency requirements empower consumers with meaningful, actionable, personalized information to help them make better informed decisions about cost and quality of health care services. A 2019 AHIP survey demonstrated 75 percent of commercial health insurance issuers offer an enrollee cost calculator tool.[3] We generally support the cost calculator requirements under the Transparency in Coverage final rule and are committed to expanding access to consumer-facing tools. CMS should make targeted changes to the requirements of the final rule to ensure online cost calculator tools focus on the most impactful, most in-demand cost information and allow issuers to display information in a way that will be most accurate and meaningful. First, CMS should require a focused set of 500 shoppable services in issuer online cost calculator tools for implementation January 1, 2023, not the earlier date in the No Surprises Act, and not require all items and services. Issuers' experiences with existing cost calculator tools demonstrates most consumer searches are for a small subset of common services like office visits, elective surgeries, imaging, and preventive care that can be researched in advance. Second, CMS should provide issuers flexibility to apply sophisticated methodologies including advance analytics to more accurate estimate enrollee cost-sharing based on a range of inputs, rather than forcing estimates to be developed based only on negotiated rates.

[3] AHIP Price Transparency Tool Survey of member health insurance plans fielded December 5, 2019 to January 10, 2020.

We strongly recommend the Administration rescind the requirement for public disclosure of privately negotiated rates and instead refocus on consumer-centric transparency tools. While intended to drive competition and foster development of transparency tools by making relevant data publicly available, the Transparency in Coverage final rule requirement for public disclosure of in-network rates, out-of-network allowed amounts, and prescription drug rates is not a well-considered approach and would provide consumers with inaccurate information.[4] Sharing negotiated rates or historical net prices via machine readable files would not provide consumers meaningful, accurate, personalized information on their estimated costs. Consumers seeking information on their potential health care costs are most concerned with their out-of-pocket costs. Moreover, policies designed to push personal information to technology companies to monetize without appropriate privacy and security guardrails leave consumers vulnerable. Under these requirements, sensitive enrollee data, at an individually-identifiable level, will flow from payers to non-HIPAA regulated entities that are not required to protect consumer privacy and could, for example, freely sell the data as long as that potential use is noted in the terms and agreement. Lastly, these policies largely ignore the broader trend toward value-based care that begins to sever the reliance on fee-for-service and move toward risk-based arrangements, where prices for individual items and services become obsolete.

The Administration should refocus the federal transparency strategy to prioritize consumers by implementing solutions that provide consumers personalized, accurate, actionable information while protecting their privacy. The availability of machine-readable files with specific payment amounts for every single item or service provided by every single provider and facility for every individual and employer plan will not be useful to health care consumers. Public disclosure of negotiated rates will likely lead to consumer confusion rather than empowerment because consumers will not be able to apply their plan benefits and determine their out-of-pocket costs from this information. Consumer-facing tools like issuer cost calculators and advanced explanations of benefits (EOBs) will provide enrollees with personalized, meaningful information on their estimated costs. Issuers are allocating significant resources to develop, build, test, and deploy those consumer-facing tools. **If CMS proceeds with implementing the requirement for public disclosure of rates, the approach should be fundamentally redesigned and implemented after consumer-facing tools are implemented.**

Technical Comments on Machine-Readable File Requirements

If CMS requires disclosure of negotiated rates via machine readable file, several foundational technical issues must first be addressed.

CMS should evaluate hospital machine-readable files to better understand the challenges of publicly disclosing rates in this format and apply lessons learned before implementing issuer machine-readable files. Hospitals began posting machine-readable files to publicly disclose rates on January 1, 2021. Thus far, we have identified several challenges and limitations with implementation of hospital files. Preliminary analysis reveals variation in underlying assumptions and display of information on allowed amounts and standard charges. Variation in a hospital's assumptions and inputs—such as inclusion of physician costs—lead to wide variation on costs displayed in machine-readable files. If interpreted by a third-party app developer or technology company and displayed through an app, consumers will not see apples-to-apples comparisons of cost information. To avoid replicating these challenges, CMS should examine the usefulness of the type, amount, and format of data disclosed through hospital machine-

[4] It also would raise significant legal issues, a number of which were discussed in our comment letter on the draft rule (https://www.ahip.org/wp-content/uploads/AHIP-Transparency-in-Coverage-Comment-Letter-Final-1-29-20.pdf) and some of which arose in the final rule with the addition of the public disclosure of negotiated prescription drug rate, as well as historical net price information.

readable files and apply those lessons learned to implementing issuer machine-readable files at a later date.

The machine-readable files envisioned in the final rule and this PRA do not align with the way commercial health insurance providers reimburse for services. Unlike federal programs, where CMS applies a consistent payment methodology across hospitals, commercial health insurance providers use a mix of different methodologies across hospitals and services. The data elements proposed do not reflect these varying methodologies. As proposed, each issuer would be required to make decisions about how to reflect this variation, which would result in cost differences across providers and issuers. Ultimately, variations in issuers' assumptions or reporting methodology could result in seemingly wide variations in costs displayed to consumers that are not necessarily reflective of variations in actual costs. Importantly, machine-readable files reinforce fee-for-service (FFS) reimbursement methodologies and undermine efforts to shift toward value-based payments. More complex reimbursement methodologies like bundled payments or capitated arrangements would be much more difficult to reflect in the proposed machine-readable file layouts.

The proposed data elements and file layout do not reflect how issuers develop rates by network or formulary and would create unnecessarily large and complex files. One notable flaw in the proposed data elements and file layout is the requirement to report information on "Identification of Plan or Coverage" in all three machine-readable files. We recommend this section be eliminated from the files. Negotiated rates vary based on network or formulary—not the plan or coverage—and fee schedules or rates can be common across groups or plans. Requiring data to be reported by employer identification number (EIN) or HIOS ID, thus linking to the group or plan rather than network or formulary, would result in a large volume of information repeated over and over, making the files exponentially larger than necessary with no perceivable benefit to the end user. If plan and coverage information must be reported, it could instead be listed in a fourth, separate file and mapped to the appropriate network or formulary, rather than being repeated over and over throughout each of the In-Network, Allowed Amount, and Prescription Drug files. This information could then be mapped from the separate file to the appropriate network. Removing this section entirely or relocating this data to another file could remove one layer of complexity and reduce the volume of records in each file.

The machine-readable files would create tremendous administrative burden for issuers without a corresponding benefit to consumers and they cannot be implemented by January 1, 2022. Issuers estimate In-Network Rate Files could include over a billion records for a single-state issuer and tens of billions of records for large multi-state issuers, while the Allowed Amount and Prescription Drug Files would each contain hundreds of millions of records. In response to the proposed rule, issuers estimated an average cost of $2.1 million to develop the In-Network Rate and Out-of-Network Allowed Amount Files. Half of issuers estimated it would take at least two years to implement these requirements while an additional 13 percent estimated it would take at least 18 months after final guidance.[5] The final rule requires a third file, the Prescription Drug File, and expands the requirements for the Allowed Amount File. While we have not updated our cost and burden estimates through a formal survey, issuers expect costs to implement the files in the final rule would be greater due to the added file and new complexity. Creating three files with this volume and complexity of data, with technical details not yet finalized and implementation questions unanswered, is not possible by January 1, 2022. Issuers are already resource-constrained while responding to the COVID-19 public health emergency and simultaneously working to implement other important consumer-facing requirements like interoperability and recent surprise billing protections included in the No Surprises Act. We urge CMS to prioritize activities that have a direct consumer impact like surprise billing protections over machine readable files.

[5] AHIP Price Transparency Tool Survey of member health insurance plans fielded December 5, 2019 to January 10, 2020.

AHIP and our member health plans are committed to empowering consumers with personalized, meaningful information on their out-of-pocket costs so they can make an informed decision about cost and value when seeking health care. We do not believe disclosure of negotiated rates through machine readable files meets that goal and strongly urge CMS to rescind this requirement or halt implementation while reconsidering the approach through notice and comment rulemaking. We appreciate the opportunity to comment on the machine-readable file requirement and are committed to continuing to work with the Administration on advancing a consumer-focused transparency framework.

Sincerely,

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Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

RE: Transparency in Pricing Information (CMS–10715) – Paperwork Reduction Act

Dear Acting Administrator Richter:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to provide additional comments on the Paperwork Reduction Act (PRA) notice (CMS-10715) published on Dec. 30, 2020.

BCBSA is a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield (BCBS) companies (Plans) that collectively provide health care coverage for one in three Americans. For more than 90 years, Blue Cross and Blue Shield companies have offered quality health care coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid.

We support the goal of greater information access to empower consumers to make the best choices for their care and to evaluate the quality of their providers. BCBS companies have a long-standing commitment to improving the interoperability and transparency of health care information and believe the secure and seamless flow of meaningful data among patients, doctors, hospitals and insurance companies is essential to improving decisions and outcomes in the health care market.

We support transparency done the right way – by providing consumers with secure, meaningful and actionable data that is relevant to their health care decision-making. BCBS Plans in all 50 states provide consumer-focused tools to help members estimate the range of costs for specific "shoppable" procedures across providers in their communities. Shoppable services are non-emergent and are typically offered by multiple providers in a region so consumers have an opportunity to consider several providers and delivery settings prior to receiving care. Many

existing health plan tools also estimate costs based on the best available data and use innovative approaches to give the most meaningful estimate prior to having the detailed nuances of how the service is administered, typically relying on claims history and average total treatment costs that a member can typically expect when seeking a service. Plans are continuously working to innovate and improve their consumer tools, incorporating ongoing requests, feedback and insights from their members. Our experience tells us consumers most want clear information about their out-of-pocket (OOP) costs, the quality of care provided and whether providers are in-network.

While we support the goals of the Transparency in Coverage rule, we are concerned that certain requirements would not support effective consumer decision-making, while imposing costly, unworkable and unnecessary burdens on stakeholders, diverting resources from efforts already under way to develop more sophisticated consumer transparency solutions, and jeopardizing efforts to enhance consumer privacy and security of sensitive information.

Furthermore, the Consolidated Appropriations Act (CAA) that Congress signed into law on Dec. 27, 2020, creates a number of new transparency components that interact with the Transparency in Coverage rule (rule). To ensure health plans are providing the clearest, most meaningful information for consumers, it is critical that these new requirements are fully integrated with the interoperability and transparency work already underway. With these goals in mind, in the next section, we outline our recommendations for streamlining the Transparency in Coverage and CAA requirements.

Recommendations for Streamlining the Transparency in Coverage and CAA Requirements

To support the most effective, consumer-friendly and secure approach to streamlining the Transparency in Coverage and CAA requirements, we recommend the Department of Health and Human Services (HHS), in coordination with the Departments of Labor and Treasury:

- **Eliminate the requirements for health plans to generate and publicly post machine-readable files**. With the enactment of the CAA, we believe the urgency for making this information available is mitigated by the advance explanation of benefit (EOB) requirements. These estimates will provide patients with the negotiated rate information specific to their needs and within the context of their own benefits and coverage. As such, we encourage the agencies to eliminate the machine-readable file requirements. This will reduce duplication of efforts while ensuring consumers have the data points they need to make an informed decision.

  Furthermore, these files are likely to lead to misleading information being provided to consumers in the market. The way the information is required to be included in the files is overly simplified and, as such, not useable by third parties to generate meaningful information for consumers. The industry is already seeing this confusion play out with the hospital transparency rule (and the machine readable files that hospitals are required to report for a small subset of services), and it is likely that the payer file will lead to similar or greater confusion given the magnitude of the number of items and services that payers are required to report. The file expects one price per billing code to represent the price of an item or service, when often, member attributes or a combination of billing codes and modifiers are used to determine pricing. Prices also are structured using formats that are not

easily converted to a static number, but instead are based on complex systems driven by pricing rules and logic (e.g., the relationship of the services billed to each other, the level of service, the acuity of the case). This creates many instances where what is displayed as the negotiated rate in the file may be one possibility, but do not reflect the only possible amount. One Plan noted that a single Diagnosis Related Group (DRG), could result in pricing between $12,000 to $120,000, based on applying these other factors, which are not included in the files. Yet, the current regulatory requirements also do not allow for providing an average or relying on trends in historical claims data to make the information more meaningful.

Similarly, the out-of-network provider file asks for averages of claims data to report allowed amounts. Calculating these amounts will be extremely complex and likely not done in a consistent way across health plans, creating potential issues with the accuracy within the files, but also their comparability if a third party expects to be able to draw findings across issuers. Making this information publicly available is likely to confuse and mislead consumers and any potential benefit is ameliorated by health plans already generating advance EOBs.

Finally, it is critical that patient privacy is protected. The Transparency in Coverage rule allows third parties to access and use patient health information through the machine-readable files without the needed updates to privacy laws or federal oversight to ensure patient health data is protected and secure. Removing these requirements will help ensure patients' privacy and the appropriate use of the data.

- **If the rate publication requirements are retained, establish a glide path for health plans to use a Fast Healthcare Interoperability Resources (FHIR)-based Application Programming Interface (API) transfer rather than generating machine-readable files.** As a whole, the industry is moving away from machine-readable files and working to support API data transfers consistent with new federal interoperability regulations. Understanding that the necessary FHIR standards are not yet in place, we encourage the agencies to provide health plans with a glide path to move towards FHIR-based API transfers. As part of this glide path, HHS should align the Health Insurance Portability and Accountability Act (HIPAA) privacy and security standards for all third-party applications used to facilitate consumer cost information including third-party applications that facilitate access to machine-readable files.

- **Focus the comparison tool on 500 shoppable services and allow greater flexibility in how estimates are calculated.** As mentioned earlier, we strongly support greater transparency and are committed to providing consumers with the health care quality and price information they want and need to make the best decisions for themselves and their families. To support these goals, we believe consumer transparency should focus on the shoppable services to reduce the noise of additional complicated health services for which price comparison is not feasible. Our real-world experience with existing health plan consumer transparency tools indicates more than 80 percent of consumer searches are for 50 services, a small subset of the more than 1,600 shoppable services that are available today. As examples, shoppable services include office visits, knee surgeries, MRIs and preventive care where consumers have advanced knowledge of the care they need and can research the costs in advance. Non-shoppable services might include emergency room

visits, rare treatments only offered by a very limited number of providers or subcomponents of care delivered within a care visit, like the cost for a specific anesthesiologist.

In addition, the rule requires health plans to provide information on covered items and services based on billing codes rather than user-friendly terminology and curated service estimates based on what services members can reasonably be expected to require. Some plans have indicated they would be forced to run two sets of tools – one designed to meet member shopping needs and another implemented only to meet the requirements of the rule, which would provide little value to the consumer and few members would use. Plans also would not be able to leverage claims history, as is done currently, to provide the most accurate reflection of a member's likely costs. It is important that increased transparency brings down costs and provides patients with better, more coordinated care. Building tools based on searching by billing codes, requiring health plans to assign discrete dollar values to all items and services – regardless of the contracting model – and not allowing health plans to rely on the best data available will likely confuse and frustrate consumers and also may suppress the movement towards value-based care.

Finally, we are not aware of any existing transparency technology solutions that support the level of information ultimately required for the rule-compliant tools – nor would such a thing be useful as much of the required information could confuse and mislead consumers and the costs to implement would be enormous. As discussed in the next section, the average of the total setup and maintenance costs for carriers to comply with the rule was estimated to be more than $13.63 million – 26 times what the Tri-agencies estimated the costs to be.

- **Align enforcement of the CAA price comparison tool requirements (Sec. 114) with the Transparency in Coverage rule implementation timelines.** Health plans are working to implement the substantial requirements for consumer tools outlined in the rule, which requires health plans to have their initial tools, comprising the required 500 shoppable services, for plan years starting in 2023. The 2023 effective date was established by the agencies based on an understanding that any more aggressive timeline simply was not feasible. However, the CAA requires the comparison tool to be implemented for 2022, a full year earlier, and is not limited to the 500 shoppable services. We urge the agencies to align their enforcement of the CAA price comparison tool requirements with the rule timelines to ensure the tools can be implemented effectively and prevent unnecessary confusion for consumers.

- **In addition to guidance on what is required under Sec. 114, clarify that any health plan providing a tool that meets the requirements of the Transparency in Coverage Rule be considered to meet the compliance requirement for the CAA price comparison tool provisions.** To ensure health plans are not required to produce a separate price comparison tool in addition to the tool required under the rule, substantially increasing health plan burden with no benefit for consumers, we urge the agencies to ensure that implementation of the rule requirements meets the standard for compliance with the CAA Sec. 114 requirements.

Burden Associated with the Machine-readable Files Increased by Final Rule and CAA

As mentioned, we have specific concerns regarding the requirements related to machine-readable files, which would expose massive amounts of commercially sensitive data, put

consumer health information at risk and provide little to no meaningful information that consumers could use for their decision-making.

In addition to the concerns enumerated on the files as a whole, we believe that the burden estimate for the rule grossly underestimated the burden of implementation on health plans and issuers. In our previous PRA response (please reference the Appendix), we outlined an analysis done by an independent third party, Bates White Economic Consulting, which estimated the expected costs of implementing the Transparency in Coverage Proposed Rule:

- Issuers interviewed by Bates White Economic Consulting estimated the total cost of implementing the Proposed Rule (including set-up and annual maintenance) to be more than 26 times the estimate produced by the Departments.

- The average cost estimate provided was approximately $13.632 million per issuer while the agencies' estimate was only $510,000. The agencies estimated that the annual maintenance cost for the consumer price tool alone would cost only $13,141, but the carriers included in the Bates White analysis estimated that cost, on average, at $3.8 million – an astonishing difference.

- Bates White indicated its estimated total implementation cost of the Proposed Rule was likely conservative, as it did not consider the cost to states, self-administered plans that do not use third-party administrators, or customizing unique tools for large employer accounts. It also focused solely on the operational costs of implementation and did not estimate the broader economic costs of the rule once implemented.

While these estimates alone were staggering, a number of factors since the Proposed Rule analysis was conducted indicate these costs *will likely be considerably higher*:

- **Complexity of converting non-fee-for-service pricing.** The Final Rule includes certain data definitions and elements that force health plans to expend a tremendous amount of effort to convert data from more innovative contracting arrangements and plan designs into a very rigid and detailed fee-for-service framework. As health plans get further into thinking through the implementation of these requirements, it is becoming increasingly apparent that these requirements represent a substantial resource investment to both design and maintain.

  For example, the original Bates White analysis estimated an average carrier cost of $467,000 annually to maintain the negotiated rate file alone. After additional time to consider how all of the different price models will need to be adapted to share a single negotiated rate per code, **we estimate this cost closer to $2 million annually for maintaining that single file on a monthly basis**. Health plans will be required to establish semi-manual processes outside of their claims adjudication systems to calculate these figures across all items and services and all lines of business, and the amount of data represented by that universe is staggering.[1]

[1] There are more than 94,000 codes that exist currently—77,559 ICD-10-PCS and 16,448 HCPCS (includes CPT)—covering institutional inpatient, outpatient and professional claims. Within the BCBS System alone, there are more than 2 million unique practitioners, groups of practitioners or facilities.

The costs of implementing and maintaining these files is particularly jarring given that the information in them will not be helpful, and may ultimately be more harmful, to consumers. As we are already seeing as hospitals work to comply with their more limited requirements, the information being provided is inconsistent, overly complex and, in many cases, indecipherable if one does not already have an understanding of their specific contracting arrangements. In analysis conducted of the hospital files posted to date by Anthem, at least one hospital was clear that the rates were derived (i.e., not straightforward fee schedule prices), but did not provide information on the derivation methodology, which is understandable as it was likely complex and variable. Another hospital displayed the negotiated rates as a percentage, which is likely how their contracting for some services is structured, but the underlying charges were not provided. As such, an external party would not be able to establish a dollar value for the codes. These are just two examples, but there were many more and no two hospitals' data was directly comparable. A third party attempting to use this data to compare costs across hospital providers, let alone a consumer, would not be able to generate any estimate that could be relied upon for decision-making.

We highlight these examples, not to focus on the hospitals' compliance, but to demonstrate that even with the more limited requirements hospitals have, the burden of complying with these requirements is tremendous and, in some ways, impossible. Health care services are not paid for in a manner consistent with the machine-readable file requirements. Commercial payers use a mix of different methodologies across hospitals and services and would need to find a way to reflect those varying methodologies without having all of the relevant data points and simplifying the information. By nature, this makes the figures less exact.

To illustrate the point, take the example of DRG 470 (Knee/Hip Replacement) under inpatient services. As the requirements stand, a health plan would be expected to generate a static dollar amount that potentially accounts for the following, among other variables:

- A per diem methodology, where days may be a mix of general medical/surgical can and/or an intensive care (i.e., variable levels of service).
- A case rate of up X days with per diem thereafter, without a specified number of days to be accounted for.
- Any carve-out provision for items and services, such as implants, which may be structured as a percent of charges, a fee schedule or at invoice acquisition cost plus a mark-up.
- Any stop-loss provisions that allow for additional reimbursement for outlier cases. These methodologies may be day- or charge-based, may be first or second dollar coverage and may exclude selected charges (e.g., high-cost drugs, implants) from the threshold or outlier payment.
- The potential use of All Patients Refined Diagnosis Related Groups (APG DRG) methodologies, which may have multiple rates within the same DRG.

When considering the number of provider locations and networks offered by Plans, there are more than 50 million unique combinations of provider network locations. The resulting potential universe of prices health plans are required to disclose in the machine-readable files is in the hundreds of billions.

- Any bundling across all episodic costs (including professional services).

Outpatient is even more complex with variations in the grouper methodologies, hierarchies, etc. Even if reimbursed under an outpatient provider payment schedule, services are often paid differently depending on what other services are billed with it. Some payment rates use bundling or multiple procedure discounting. Each payer will be forced to make decisions about how to reflect this variation, resulting in cost differences between providers and carriers that may be driven by reporting methodology and not the true variation in cost. This complexity is one of the reasons many existing cost calculators rely on claims history and averages to give a closer estimate on what a consumer's anticipated costs will be prior to having all of the data points.

- **Addition of the Prescription Drug File.** The Final Rule included the creation of a third machine-readable file for prescription drugs that was not included in the Proposed Rule and, therefore, not accounted for in the initial implementation costs estimate. This file, in particular, will be challenging to maintain as:
  - Many health plans do not store pharmacy reimbursement rates in their systems and so will have to rely on historical data to estimate future costs. This will not ultimately reflect what a customer sees when they go purchase drugs in many instances.
  - Similar to other services, dollar amounts for negotiated rates will be challenging to define due to the complexity of pharmacy pricing. Pharmacy prices often use the lower of logic between the usual and customary price, the maximum. allowable cost or the average wholesale price discount (AWP) for that drug
  - Pharmacy prices change constantly due to AWP inflation, changes in usual and customary pricing by pharmacy as well as changes in maximum allowable costs. There are regulatory market rates changes and calibrations done to assign costs appropriately across clients and pharmacies.
  - The file will not indicate which drugs are preferred, an important data point for consumers when making decisions on their prescriptions.

- **Burden on self-funded accounts.** The requirement to create files for self-funded accounts significantly increases the volume of duplicative data that will need to be produced and imposes a considerable burden on employers to comply with the rule. Negotiated rates generally vary based on the network, not the plan or coverage. Furthermore, an individual account may have different benefit options which would, again, rely on the same rates. Potentially requiring this information to be duplicated across all plans and coverage, and within accounts, substantially increases the scale of the data to be produced with little to no demonstrable benefit to the consumer, but at great cost to plans and consumers.

The operational cost for the Transparency in Coverage rule alone in the first year is likely to exceed $27 billion given these additional factors specific to the machine-readable files alone and if the costs estimated by Bates White are multiplied by the number of insurers and TPAs reported by the Departments. That amount completely negates the $11.4 billion in regulatory

savings the Office of Management and Budget estimated for the Department of Health and Human Services under Executive Order 13771 for fiscal year 2019.[2]

However, the costs of both these requirements and the new CAA provisions will be substantially more, if even feasible within the timelines outlined. Currently, the CAA transparency requirements are not fully understood since much of the language requires clarifications from the relevant agencies. However, it is clear that some of the provisions, specifically the advance EOB and price comparison tool requirements, closely relate to the Transparency in Coverage goals and requirements. Given the current ambiguity and the aggressive implementation timeframes laid out in the CAA, these different components must reconciled with the Transparency in Coverage rule requirements thoughtfully and in a timely manner. Otherwise, they will impose significant and likely duplicative burden on health plans to implement and confusion for members once available.

In what follows, we offer detailed recommendations regarding the specific information files in the Paperwork Reduction Act that the Centers for Medicare & Medicaid Services (CMS) requested feedback on, and for use if the machine-readable files continue to be required.

[2] Regulatory Reform Under Executive Order 13771: Final Accounting for Fiscal Year 2019.

Appendix 2: In-network Rate Machine-Readable File Data Elements

Issue: The Final Rule requires plans to make available on an internet website a machine-readable file disclosing applicable rates for in-network providers, including identification of plan or coverage data elements. Within the identification of plan or coverage data elements, CMS is asking for data elements including plan or coverage name, plan identifier, type of plan identifier and type of plan market.

Recommendation #1:

We recommend CMS eliminate the "plan or coverage" data elements from the reporting.

Rationale:

Negotiated rates generally vary based on the network, not the "plan or coverage." As such, the machine-readable files would be restating the same information repeatedly, making the files exponentially larger with no perceivable benefit to the end-user. The sheer volume of data health plans would be obligated to disclose is staggering. As mentioned above, the resulting universe of prices would be in hundreds of billions, with a significant amount of duplication.

Recommendation #2:

Absent eliminating the "plan or coverage" data element, we propose adding a fourth table that would include the information separately.

Rationale:

Including this information in the Appendix would cause the files to be exponentially larger with much of the same information repeated continuously. To reduce file size and redundancies, we recommend a fourth table that would list the plan/coverage identification and then map each plan/coverage to the appropriate network.

Issue: The Final Rule requires plans to make available on an internet website a machine-readable file disclosing applicable rates for in-network providers, including plan identifier and type of plan identifier data elements. Within the plan identifier and type of plan identifier data elements Employer Identification Number (EIN) is used as a descriptor of the data element required.

Recommendation:

We ask that CMS clarify that if the same group has multiple benefit options (multiple EINs), the information would not need to be repeated for the different EINs.

Rationale:

A group plan may include multiple EINs. With disclosing multiple EINs, the machine-readable files would be restating the same information repeatedly for each benefit option, making the files exponentially large with no perceivable benefit to the end-user.

Issue: The Final Rule requires plans to make available on an internet website a machine-readable file disclosing applicable rates for in-network providers, including type of billing code data elements. Within the type of billing code data elements, current procedural terminology (CPT) code is used as a descriptor of the data element required.

Recommendation:

We ask that CMS clarify if the intent of this data element is to average a provider over the same CPT regardless of modifiers and units.

Rationale:

Rates may vary based on a modifier applied to a CPT code, or based on "units," such as with anesthesia. Without using a limited number of codes or variations, the machine-readable files would be restating the same information repeatedly, making the files exponentially larger with no perceivable benefit to the end-user, or, if reporting a single value, making the information significantly less meaningful on a practical level.

Appendix 3: The Allowed Amount Machine-Readable File Data Elements

Issue: The Final Rule requires plans to make available on an internet website a machine-readable file disclosing allowed amounts and billed charges for out-of-network providers, including identification of plan or coverage data elements. Within the identification of plan or coverage data elements, CMS is asking for data elements including plan or coverage name, plan identifier, type of plan identifier and type of plan market.

Recommendation:

We recommend aligning this file with the changes proposed for the other two files, namely removing the plan or coverage fields or moving them into a separate file.

Rationale:

As mentioned for the in-network and also applicable to the pharmacy files, reporting by plan or coverage would create significant redundancy in the information, with no meaningful benefit, and so these data elements should be removed from those files or reported in a separate fourth table. The information in the allowed amount file should be similarly reported to be consistent with the other two files.

Issue: The Proposed Rule requires plans to make available on an internet website a machine-readable file disclosing allowed amounts and billed charges for out-of-network providers, including identification of providers and place of service as well as historical out-of-network allowed amounts data elements. Within the identification of providers and place of service as

well as historical out-of-network allowed amounts data elements, CMS is asking for data elements specific to provider information.

Recommendation:

We recommend CMS consider eliminating the provider information from the file.

Rationale:

Disclosing out-of-network allowed amounts by CPT code would be more meaningful than by provider as claims history may not be available for each out-of-network provider and would likely not reflect the best estimate of a likely out-of-network cost for the service.

Appendix 4: Prescription Drug Machine-Readable File Data Elements

Issue: The Proposed Rule requires plans to make available on an internet website a machine-readable file disclosing in-network drug prices, including identification of plan or coverage data elements. Within the identification of plan or coverage data elements, CMS is asking for data elements including plan or coverage name, plan identifier, type of plan identifier and type of plan market.

Recommendation #1:

We recommend CMS eliminate the "plan or coverage" data elements from the reporting.

Rationale:

Negotiated rates generally vary based on the network, not the "plan or coverage." As such, the machine-readable files would be restating the same information repeatedly, making the files exponentially larger with no perceivable benefit to the end-user. The sheer volume of data health plans would be obligated to disclose is staggering. As mentioned above, the resulting universe of prices would be in hundreds of billions, with a significant amount of duplication.

Recommendation #2:

Absent eliminating the "plan or coverage" data element, we propose adding a fourth table that would include the information separately.

Rationale:

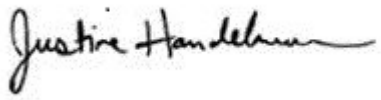
Including this information in this Appendix would cause the files to be exponentially larger with much of the same information repeated continuously. To reduce file size and redundancies, we recommend a fourth table that would list the plan/coverage identification and then map each to the appropriate network.

* * *

Thank you for the opportunity to provide detailed comments and recommendations. We look forward to continuing to work with the agencies to advance our shared goal of providing consumers with meaningful and actionable information so they can make the best decisions for

themselves and their families. If you have questions, please contact Anshu Choudhri at 202.626.8606 or Anshuman.Choudhri@bcbsa.com.

Sincerely,



Justine Handelman
Senior Vice President
Office of Policy and Representation

Appendix: Independent Assessment of Economic Burden of Proposed Transparency in Coverage Rule (January 20, 2020)

Estimating the Burden of the Proposed Transparency in Coverage Rule

Arun Sharma

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January 22, 2020

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Table of Contents

I. EXECUTIVE SUMMARY

Driven by concerns about health care expenditures and the difficulties individuals encounter in obtaining information in advance about the cost of health care goods and services, the Administration has proposed a new "Transparency in Coverage" rule (TCR). These regulations would require two things from carriers offering health plans: (1 a consumer tool that allows carrier members to prospectively identify their specific out-of-pocket (OOP) cost for any health care services or goods covered by their health carrier; and (2 two publicly-available machine-readable data files. One of these files (the Negotiated Rate File) lists negotiated prices for all covered goods and services for all health care providers in the insurance carrier's network. The other file (the Allowed Amount File) reports the amount that the insurer has historically paid for covered items and services delivered by providers not included in the carrier's network.

The economic issues involved in transparency in health care coverage have been discussed in academic literature, and there are many important financial and economic issues related to transparency that we do not consider here. Among these are the potential impact of disclosing confidentially negotiated rates for hospital and provider payment; economic implications for the cost and quality of care resulting from releasing negotiated rates between providers and payors; potential legal costs; and customer experience issues arising from a regulatory approach that potentially conflicts with existing market driven efforts. This paper is focused on assessing the administrative and operational costs of implementation that are likely to be incurred by covered private carriers if the current proposed regulations are finalized without any changes.

The Proposed Rule was published by the Department of the Treasury, Department of Labor and Department of Health and Human Services (the Departments) in the *Federal Register* and includes estimated compliance costs. We have been asked to assess the costs insurers are likely to encounter and to compare those to the cost estimates in the *Federal Register*. In order to assess those costs, we conducted interviews with representatives of 18 insurance companies representing approximately 78 million members, describing the carrier requirements and asking them to provide initial estimates of the cost of establishing the tools and data files described in the regulations. The vast majority of these carriers (94.4%) already offer a consumer price transparency tool, providing OOP cost information on an average of 1,011 items and services.

Through our interviews, we found that insurance companies anticipate a much greater burden for establishing and maintaining the tool and the data files required by the regulation, by a factor of about 26, than is estimated in the Proposed Rule. The table below summarizes the results of our interviews.

Tool element	OMB cost estimate	Carrier cost estimate average	Carrier cost estimate range
Set up web-based consumer price tool (full build)	$221,029	$5,528,000	$1,000,000 to $15,000,000
Set up negotiated rate file	$107,905	$2,139,167	$85,000 to $10,000,000
Set up allowed amount file	$117,757	$1,071,167	$42,000 to $5,000,000
Annual maintenance of web-based consumer price tool	$13,141	$3,784,375	$375,000 to $10,000,000
Annual maintenance of negotiated rate file	$36,022	$467,000	$15,000 to $1,000,000
Annual maintenance of allowed amount file	$14,698	$643,000	$15,000 to $1,500,000
Total	$510,552	$13,632,708	-

In view of the fact that carriers are of widely varying sizes, have different levels of experience and have engaged in different levels of analysis of the impact of these newly proposed regulations, there are differences in the extent to which carriers have evaluated the costs and feasibility of complying with the regulations. The carriers also make different assumptions about the degree of support from vendors or trade associations that affect their perception of the administrative and operational costs of implementation.

Primary Conclusions:

- Carriers we interviewed anticipated the implementation costs of the TCR requirements to be substantially larger than the costs estimated by the Departments. Although the responses we received vary in their precision, the total estimated cost of complying with the proposed rule (including set-up and annual maintenance) as estimated by the carriers was $13.6 million, more than 26 times the estimate produced by the Departments.
    - The average of the estimated set-up costs provided by carriers was approximately $8.74 million, while the Departments' estimated set-up costs totaled $447,000, assuming the carrier needed to build a complete consumer tool.[3]
    - The difference in the estimates of annual maintenance costs is quite significant. The Departments estimated that the annual maintenance costs for the consumer price tool would be about $13,000, but the average of the carriers' estimates was $3.8 million, about 288 times higher. The annual maintenance costs for the two machine-readable files were also viewed as significantly more costly by the carriers.
- Carriers viewed the Consumer Search Tool as much more expensive (by a factor of more than twenty-five) to operationalize than estimated by the Departments. Although most of the carriers we spoke with have an existing consumer facing tool meeting many of the required elements of the TCR, several carriers expressed significant concern about the cost and feasibility of complying with the requirements as written. Importantly, many respondents indicated that the detailed specifications of the requirements may necessitate a complete rebuild of their consumer tool. Key concerns include:

[3] As discussed below, the Departments estimated that the set-up cost for a partial build of a consumer tool was $55,260.

- As written, the TCR references providing pre-service estimates of *all* services (discrete or bundled) that would be covered. This requires a carrier to essentially engage in a mock claim adjudication which can be highly complex depending on the goods or services involved.
- This requirement involves costly and complex integration of benefits that are not uniformly maintained within existing systems. Pharmacy benefits, benefits provided through third-party administrators, medical management requirements, visit limits and allowed out-of-network benefits were key elements of concern.
- There seems to be a core set of functions for a core set of services that the majority of respondents report having currently. These include the ability for members to: (1 learn about their OOP costs for certain items and services; (2 search for items and services by provider and by descriptive terms; and (3 filter and sort by geography, OOP costs, and distance. The carriers we interviewed typically focus on "shoppable" and commonly utilized items and services (or in some cases, procedures and bundles). In our sample, consumer tools currently provide OOP cost information on an average of 1011 items and services.[4]
- The requirement does not appear to recognize the unavoidable uncertainty in defining and pre-determining the precise services that may be provided in a given care setting. This uncertainty greatly complicates providing precise estimates of cost in many settings. One knee replacement, or one child birth, will not be the same as others, for example. It will be difficult to communicate to customers what the cost of their precise experience will be in any matter in which there is a need for provider decisions and adjustment to medical circumstances that cannot be known in advance. Some respondents indicated that inputs from providers such as diagnosis codes may be necessary to reflect the degree of precision specified in the rules.
- Multiple respondents indicated that they have existing business strategies focused on increasing cost transparency for members in a way that enhances the consumer experience. They have concerns that certain TCR requirements are inconsistent with those strategies and would require changes in customer service priorities that they see as detrimental to care and the customer experience.

- Carriers viewed the Negotiated Rate File as much more costly to implement (by a factor of approximately twenty) than estimated by the Departments. Carriers estimated set-up costs surpassing $2 million, on average. Annual maintenance costs were also estimated to be much higher at $467,000, about 13 times higher than the Departments' estimate. While not quantifiable, some respondents indicated that certain aspects of this portion of the Proposed Rule are not feasible. For example, they noted that negotiated rates for performance-based (quality-adjusted) and experience-based (risk-adjusted) contracts can only be calculated ex-post and would not necessarily reflect rates going forward.
- Generally, we found that interview respondents shared consistent concerns about the high cost and significant complexity associated with producing the Allowed Amount File. While no carrier had carefully evaluated the cost of publishing such a file, carriers estimated set-up costs of over $1 million (about nine times higher than estimated by the Departments) and annual maintenance costs of $643,000 (44 times higher than the Departments' estimate). In addition, some respondents expressed concerns about maintaining HIPAA protections because of the small numbers of claims associated with particular services and out-of-network providers.

[4] One interviewed carrier does not have a consumer tool; the average was calculated including zero for that carrier. Among the carriers that do have a consumer tool, the number of items and services for which OOP cost information is provided ranges from 148 to approximately 1600.

II. OVERVIEW AND SCOPE

On Nov. 15, 2019, the Departments of Health and Human Services (HHS), Treasury, and Labor released a proposed "Transparency in Coverage" rule (TCR).[5] On Nov. 27, 2019, TCR was posted in the *Federal Register* and the Departments are seeking comments by 5 p.m. on Jan. 29, 2020.[6]

Bates White was asked by the Blue Cross Blue Shield Association (BCBSA) and America's Health Insurance Plans (AHIP) to conduct an analysis of the feasibility and costs of implementing necessary changes under the proposed rule. This report summarizes the results of that evaluation, which was conducted by interviewing representatives of 18 carriers that are members of BCBSA and AHIP. We refer to these interview respondents as "carriers" throughout. Efforts were made to include carriers with a wide range of characteristics, such that our sample is roughly representative of all carriers offering a variety of health insurance coverages.

The carriers we interviewed span the range of small to large insurers. Our interview respondents cover a total of more than 78 million lives in the U.S. and range from a low of under 300,000 to a high of more than 25 million covered lives per carrier. Interviewed carriers included both national and individual state carriers and offered a variety of coverage designs including group and individual coverage in a variety of formats in both the private and public sectors.

Each interview was scheduled for one hour. In view of the relatively short time since the Proposed Rule was released, most carriers have not undertaken formal cost estimation analyses and have not formally begun implementing system changes or negotiating with third parties regarding system and data upgrades. Thus, the figures reported here represent the carriers' best approximations of the operational costs involved in implementing the new regulations at this time and should be interpreted as preliminary estimates that are subject to change. Carriers emphasized that their estimates are based on the assumption that no major unforeseen problems occur. Thus, their estimates are believed to be conservative and could be significantly higher, especially for those aspects of the Proposed Rule for which feasibility is not assured. Further, carriers were asked to describe the feasibility and costs associated with implementing the Proposed Rule as it currently stands, despite the fact they expect certain elements of the regulations to be clarified, modified or eliminated.

This report: (1 summarizes the current state of BCBSA and AHIP carriers' price transparency efforts and evaluates the feasibility of meeting specific requirements of TCR within one year of when it is finalized; (2 compares the cost estimates provided by carriers with those calculated by the Departments; and (3 identifies areas in which the carriers interviewed believe the Departments' estimates appear to be reasonable, understated, overstated or incomplete. A complete analysis of the economic implications of the Proposed Rule, such as the potential impact on the prices carriers negotiate with hospitals and practitioners, is beyond the scope of this report, which only considers the administrative and operational challenges involved in compliance.

The remainder of this report is organized as follows.

- Section III describes the requirements imposed by TCR on all health insurance issuers and Third Party Administrators (TPAs) and then summarizes the Departments' estimates of the incremental burden associated with these requirements.
- Section IV reviews the *Federal Register* estimates of the burden imposed by the TCR rule.

[5] U.S. Department of Health & Human Services, "Trump Administration Announces Historic Price Transparency Requirements to Increase Competition and Lower Healthcare Costs for All Americans," news release, Nov. 15, 2019, *available at* https://www.hhs.gov/about/news/2019/11/15/trump-administration-announces-historic-price-transparency-and-lower-healthcare-costs-for-all-americans.html

[6] Transparency in Coverage, 84 Fed. Reg. 229 (November 27, 2019). p. 65464

- Section V begins by summarizing the state of existing web-based consumer tools among the carriers interviewed—outlining specific TCR requirements that would require additional investment. Then, before getting into cost estimates, we summarize existential issues that are introduced by specific TCR requirements. The section concludes by presenting cost estimates provided by carriers and compares these estimates with those provided by the Departments for the average carrier.
- Section VI details our conclusions.

III. PROPOSED TCR REQUIREMENTS

TCR imposes three significant requirements. Group health carriers and health insurers must: (1 develop, build and maintain an internet-based consumer self-service tool that makes cost-sharing information available to plan members; (2 make publicly available a machine-readable Negotiated Rate File; and (3 make publicly available a machine-readable Allowed Amount File.[7] If unchanged in the Final Rule, these requirements will go into effect for plan years beginning one year after the rule is finalized.[8]

III.A. Consumer-facing Search Tool

The consumer self-service tool would require carriers to provide covered individuals with cost and eligibility information before receiving services. The tool is required to have the following features:

- Calculate OOP costs for all items and services defined as: all encounters, procedures, medical tests, supplies, drugs, durable medical equipment and fees (including facility fees), for which a provider charges a patient in connection with the provision of healthcare.
- Estimate allowed amounts and a plan member's cost-sharing liability for all out-of-network items and services, by provider, using historical claims data.
- Ability for plan members to search for items and services by provider, billing code or descriptive terms, and by any other factor necessary for determining the cost sharing amount.
- Ability for plan members to filter and sort by geographic proximity, OOP costs and distance.
- Communicate progress towards both individual and family deductibles and out-of-pocket maximums.
- Communicate medical management prerequisites for services to be covered.
- Provide estimates based on provider tier.
- Communicate applicable visit limits and deductibles in real time.
- Provide all of the information from the web-based consumer tool on paper, within two days, upon request.[9]

III.B. Negotiated Rate File

The regulations require all carriers to produce a machine-readable file provided in the public domain that includes negotiated rates for each covered item or service furnished by in-network providers. Data in this file is to be expressed as a dollar amount associated with the provider's National Provider Identifier (NPI). If the carrier or issuer uses a bundled payment rate, the carrier must identify the items included in each bundle of services by the relevant code.[10]

This file "must be posted on a public internet site with unrestricted access and must be updated monthly."[11] The purpose of this tool is to allow third parties to access up-to-date price and cost information across different carriers. While the file would not be in a format conducive to use by consumers, it would be useable by parties developing cost-comparison tools and other applications of use to consumers and would also become publicly

[7] Transparency in Coverage, 84 Fed. Reg. 229 (November 27, 2019). p. 65469-65470
[8] Transparency in Coverage, 84 Fed. Reg. 229 (November 27, 2019). p. 65516
[9] Transparency in Coverage, 84 Fed. Reg. 229 (November 27, 2019). p. 65471-65474
[10] Transparency in Coverage, 84 Fed. Reg. 229 (November 27, 2019). p. 65479
[11] Transparency in Coverage, 84 Fed. Reg. 229 (November 27, 2019). p. 65507

available to all carriers and providers. The data in the file would also be useable by health services researchers and others analyzing the performance of the U.S. health care system.

III.C. Allowed Amount File

Carriers are also required to produce and maintain a publicly available machine-readable file that provides amounts payable for covered items or services associated with particular out-of-network providers. These data are to be calculated by assessing historical cost during the 90-day period that begins 180 days before the publication date of the Allowed Amount File. Amounts are to be expressed as a dollar amount and are to be associated with the provider's NPI. This amount would include the carrier's paid portion and the plan member's share of costs.[12]

This file must be published and updated similarly to the Negotiated Rate File. As with the Negotiated Rate File, this information would generally not be in a format conducive to use by typical consumers, but it would be useable by third parties for similar purposes to those described for the Negotiated Rate File.

[12] Transparency in Coverage, 84 Fed. Reg. 229 (November 27, 2019). p. 65480

IV. *FEDERAL REGISTER* ESTIMATES OF BURDEN

As required by the Paperwork Reduction Act of 1995, the Departments have included estimates of the burden of complying with the regulation because of Executive Order 12866 which was then reviewed by the Office of Management and Budget (OMB).[13] The Departments assessed that approximately 1,754 issuers and 205 TPAs will be affected by TCR.[14] In addition, the Departments provided estimates of the number of labor hours and costs necessary for a carrier to establish and maintain the tools and files required by the proposed regulations. These estimates are broken down into set-up and maintenance costs by requirement and summarized in Figure 1 as the average burden per health insurance issuer.[15]

In order to generate estimates of cost, the Departments estimate the average number of labor hours necessary to comply with the proposed regulation, by occupation/level. Then, the Departments use wage data from the Bureau of Labor Statistics (BLS) to map these labor hour estimates to a cost estimate.[16] Additionally, the Departments assume for a partial build that existing systems would already have operational capabilities that meet approximately 75 percent of the requirements in the Proposed Rule and, thus, the burden of a partial build would be 25 percent of a full build.

The Departments estimate that set-up for a web-based consumer tool will cost health insurance issuers an average of $221,029 for a full build and $55,260 for a partial build. The asserted burden in terms of labor hours (underlying the cost estimates) are 2,508 (1.2 FTEs) and 815 (.39 FTEs) for the full and partial builds, respectively.[17]

The rate files are also estimated to impose a moderate burden on health insurance issuers. Set-up for the Negotiated Rate File is estimated to cost health insurance issuers $107,905, on average, with a labor burden of 1,190 hours (.57 FTEs). Set-up for the Allowed Amount File is estimated to cost health insurance issuers $117,757, on average, with a labor burden of 1,290 hours (.62 FTEs). Thus, the Departments estimate the rate files required by TCR to be the larger burden of the Proposed Rule if a given health insurance issuer already has a partial build of their web-based consumer tool.

Annual maintenance of the web-based consumer price tool is estimated to cost health insurance issuers $13,141, on average, with a burden of 145 hours (.07 FTEs). Maintenance of the Negotiated Rate File is estimated to cost health insurance issuers $36,022, on average, with a labor burden of 360 hours (0.17 FTEs). Maintenance of the Allowed Amount File is estimated to cost health insurance issuers $117,757, on average, with a labor burden of 1,290 hours (.62 FTEs).

Apart from building and maintaining the web-based tool and the two rate files, the Departments included two other burden estimates: (1 Training customer service representatives on the consumer price tool was estimated to require 20 hours (with a cost of $701); and (2 Accepting and fulfilling requests for a mailed disclosure on an annual basis (labor, printing and materials) was estimated to require 15 hours annually (with a cost of $547).

As we will describe in the next section, these amounts are significantly lower than our sample of carriers anticipate. For several companies, implementing the requirements as they are currently described seems infeasible within the time frame envisioned. For others, the feasibility of implementation has not been assessed, but upon considering the requirements, the cost appears very large, “a whole new ballgame,” as one representative characterized it.

[13] Transparency in Coverage, 84 Fed. Reg. 229 (November 27, 2019). p.65491
[14] Transparency in Coverage, 84 Fed. Reg. 229 (November 27, 2019). p. 65500-65502
[15] For simplicity, we use the term “health insurance issuer” to describe one of the 1,959 issuers and TPAs the Departments had in mind while estimating costs.
[16] Mean wage estimates by occupation/level include a 100 percent increase for fringe benefits and overhead.
[17] An FTE is assumed to work 2,080 hours a year.

Figure 1: The Departments' estimates of burden associated with Proposed TCR

Requirement	Total cost per carrier	Burden per carrier (hours)
Set up for web-based consumer price tool—complete build	$221,029	2,508
Set up for web-based consumer price tool—partial build	$55,260	815
Train customer service representatives for consumer price tool	$701	20
Set up negotiated rate file	$107,905	1,190
Set up allowed amount file	$117,757	1,290
Total set up (complete build)	$447,392	5,008
Total set up (partial build)	$281,623	3,315
Annual maintenance of web-based consumer price tool	$13,141	145
Annual maintenance of negotiated rate file	$36,022	360
Annual maintenance of allowed amount file	$14,698	156
Accept and fulfill requests for a mailed disclosure on an annual basis (labor, printing and materials)	$547	15
Total annual maintenance	$64,408	676

Source: Transparency in Coverage, 84 Fed. Reg. 229 (November 27, 2019) p. 65491-65551 Notes: The Proposed Rule was published by the Department of the Treasury, Department of Labor and Department of Health and Human Services (The Departments) in the Federal Register and includes estimated compliance costs. Estimates are rounded to the nearest dollar and are provided per respondent (n=1959) where a respondent is an issuer or TPA.

V. BURDEN ASSESSED FROM INTERVIEWS

V.A. Current State of Carriers' Web-based Tools and Concerns about Certain TCR Requirements

Prior to estimating the burden of complying with TCR requirements, we assessed the state of carriers' web-based price transparency tools, if any exists. We also captured commentary on the feasibility of complying with specific TCR requirements in the timeframe in the Proposed Rule. Figure 2 summarizes carriers' responses.

Figure 2: Current state of carriers' web-based consumer tools

Functionality of current consumer tool	Percentage of carriers	Number of responses
Calculate OOP costs for certain items and services	94.4%	18
Calculate OOP costs for all items and services	0.0%	18
Estimate allowed amounts and a plan member's cost-sharing liability for all out-of-network items and services, by provider, using historical claims data.	0.0%	18
Ability for plan members to search for items and services by provider	85.7%	14
Ability for plan members to search for items and services by descriptive terms	86.7%	15
Ability for plan members to search for items and services by billing code	12.5%	16
Ability for plan members to filter and sort by geography, OOP costs and distance	84.6%	13
Communicate medical management prerequisites for services to be covered.	5.9%	17
Provide estimates based on provider tier.	22.2%	9
Communicate deductibles in real time.	46.7%	15
Communicate applicable visit limits in real time.	6.3%	16
Provide all of the information from the web-based consumer tool on paper, upon request	23.1%	13

Notes: The table above summarizes the current state of carriers' web-based consumer tools. We report the percentage of carriers offering a tool with a given functionality required by the proposed regulations and the number of respondents for each. Given that we had a limited amount of time in each interview, we did not get to ask each carrier about each functionality. In some cases, the interviewee was not sure whether the tool included certain functionalities.

V.A.1. Largest Burdens

We found that 94 percent of carriers have some sort of web-based tool for calculating a plan member's OOP costs for *certain* items and services. One takeaway from our interviews is that reporting OOP costs for *all* covered items and services poses the greatest challenge for the majority of carriers and does not provide meaningful and actionable data to the consumer. Currently, the average number of items and services for which OOP costs are provided is 1,011, with a maximum of approximately 1,600.[18] The carriers we interviewed typically focus on "shoppable" and commonly utilized items and services (or in some cases, procedures and bundles), which are more helpful to consumers.

The proposed regulations define all items and services as: "all encounters, procedures, medical tests, supplies, drugs, durable medical equipment, and fees (including facility fees), for which a provider charges a patient in connection with the provision of healthcare."[19] The proposed regulations also mention codes, including Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS) and Diagnosis-Related Group (DRG) codes. This requirement is daunting because it encompasses a very large number of potential services. One respondent said, "There are over 15 thousand codes. It would be an astronomical effort to include all services." In fact, there are more than 94,000 codes – 77,559 ICD-10-PCS and 16,448 HCPCS (includes CPT) – covering institutional inpatient, outpatient and professional claims. This does not include all of the codes connected with drugs and medical devices.

Additionally, users must be able to "search for cost-sharing information for covered items and services by billing code, or by descriptive term, per the user's request."[20] Many carriers currently allow plan members to search for items and services by provider and by descriptive terms (86 percent and 87 percent of respondents, respectively) yet not by billing code (13 percent of respondents). Apart from the efforts to develop these capabilities, concerns were raised about how consumer experience would be affected. It is unclear to many respondents how their consumer tools can remain user-friendly while also including all items and services and the corresponding billing codes. Relatedly, many health care services are subject to decision-making and judgement calls at the point of care, and it is virtually impossible to know in advance what a provider and patient may elect to do as information about a condition is revealed. In discussing this requirement, one respondent said, "a knee replacement is not a knee replacement," elaborating that the costs can vary depending on characteristics unique to the patient, which are hard to anticipate. With minor variations, this sentiment was repeated consistently. A condition requiring a bundle of services is hard to determine in advance, so providing a prospective determination of coverage and cost is very difficult.

The requirements to provide integrated information about medical management requirements, visit limits and, to a lesser extent, deductibles were also cited as significant burdens for carriers. The vast majority of carriers do not have these first two features integrated in their consumer tool today (6 percent include medical management requirements, 6 percent include visit limits, and 47 percent include deductibles). Regarding communicating applicable visit limitations, one respondent mentioned, "It would be quite a heavy lift because it's not stored in a numeric format." Complex information on benefits can vary depending on the carrier and service, and we found that it is typically not integrated with the OOP cost estimates among the carriers interviewed. It would be a large effort to integrate this information on the back-end and then make it user-friendly on the front-end.

Some respondents suggested that there would be substantial barriers in obtaining permission to disclose prescription prices, for example, from third parties (such as pharmacy benefit managers), while others seemed to

[18] Some carriers reported the number of procedures, bundles, or treatment categories so what we summarize as an "item or service" is not necessarily as granular as the proposed regulations would like.
[19] Transparency in Coverage, 84 Fed. Reg. 229 (November 27, 2019). p. 65471
[20] Transparency in Coverage, 84 Fed. Reg. 229 (November 27, 2019). p. 65501

believe they could satisfy the requirement by simply passing a customer over to the pharmacy administration website for such information without directly providing it themselves.

Providing users' cost-sharing liability for out-of-network (OON) allowed amounts was another big concern for carriers we interviewed. First, this is not something that any carriers we interviewed provide in their consumer tools today. Some respondents emphasized that historical allowed amounts with OON providers are not necessarily reflective of future cost information because carriers do not have contracts with OON providers. Thus, respondents felt that it was a risk to use historical allowed amounts in the consumer tool as an estimate, since it may be unreliable. Other respondents mentioned that it is hard to track down information on OON providers, even if they do have claims data. One respondent offered that this could potentially conflict with a current state regulation related to listing OON providers in directories.

Currently, none of the carriers we interviewed have a web-based tool anywhere close to satisfying the stated requirements of the consumer tool. Putting all of the requirements together, carriers likened the proposed regulations to mock claim adjudication. Yet, these regulations take mock claim adjudication one step further because this information would have to be user-friendly and searchable.

V.A.2. Additional Concerns

Although not uniform, a tendency among the smaller carriers we interviewed was to assume that a third-party vendor would understand the regulations and would provide an IT solution to implement necessary changes. As the details of the TCR were discussed, these carriers tended to express serious concern about the feasibility of implementation within the required length of time.

A related concern was that certain carriers employ "rental networks" which are those that provide coverage for certain services in a network arrangement rather than by individual provider. Such networks may not provide visibility to the contracting carrier of the actual rates paid for specific services within the network. Carve-out networks, where an employer carves out pharmacy or mental health to a separate vendor, could also create complicated compliance issues for employer plans. Carriers expressed concern that their ability to comply with the regulation would be inconsistent with business relationships such as rental networks or carve-outs.

Additionally, providing information from the web-based consumer tool on paper, upon request, seemed feasible to most carriers, but is not a feature of most tools currently (23 percent of those interviewed currently have capability). However, many carriers expressed concerns about the requirement to perform this task within two business days.

V.B. Cost Estimates

Figure 3 summarizes carriers' responses about the incremental burden imposed by the proposed regulations, analogous to how the Departments' estimates are summarized in Figure 1.

Figure 3: Cost estimates from carriers interviewed

Requirement	Average cost per carrier	Minimum	Maximum	Responses
Set up web-based consumer price tool	$5,528,000	$1,000,000	$15,000,000	15
Set up negotiated rate file	$2,139,167	$85,000	$10,000,000	6
Set up allowed amount file	$1,071,167	$42,000	$5,000,000	6
Total setup	$8,738,333	-	-	-
Annual maintenance of web-based consumer price tool	$3,784,375	$375,000	$10,000,000	8
Annual maintenance of negotiated rate file	$467,000	$15,000	$1,000,000	6
Annual maintenance of allowed amount file	$643,000	$15,000	$1,500,000	5
Total annual maintenance	$4,894,375	-	-	-

Notes: This Figure summarizes cost estimates provided by the carriers we interviewed. When a range of costs were given, we took the mean. If only a minimum or maximum was given, we just used that number. We conservatively assumed that a statement that a task would cost seven figures meant $1 million rather than a larger seven figure number, and that an estimate of eight figures meant $10 million rather than a larger eight figure number. If multiple ranges were added together, we took the average of each range and then summed these amounts. We also asked about the burden in terms of labor time, but the responses were harder to map to a precise number of hours or FTEs. For example, we received responses such as, “30 people would work on the project part time from multiple divisions.” Given the information we have, it is not possible to translate such responses into estimates of labor burdens.

The Consumer Search Tool was seen as much more expensive to operationalize than estimated by the Departments. Estimates of the cost averaged about $5.53 million compared to the Departments’ estimate of $221,029. This is more than 25 times what the Departments estimated as the cost for a full build of the consumer tool. Although most of the carriers we spoke with have an existing consumer-facing tool meeting many of the required elements of the TCR, several carriers expressed significant concern about the cost and feasibility of complying with the requirements as written. Multiple respondents indicated that the requirements may necessitate a complete rebuild of their consumer tool. The costs seem to be driven by two main factors: (1 the need to effectively adjudicate the claim – before it actually happens – to provide estimates for every conceivable type of medical item or service while integrating this information with various benefits; and (2 condensing all of this detail into a user-friendly format for use by enrollees, which is a considerable and possibly even infeasible challenge, as currently proposed. Many carriers indicated that, as currently worded, the proposed regulations would be more costly than implementing real-time claims adjudication, in which the claim for the medical service is adjudicated at the time the service is provided.

Given the complexities of the consumer tool, as proposed, carriers interviewed estimated the annual maintenance costs to be, on average, about $3.78 million (although fewer carriers had an estimate for maintenance costs). The Departments, by contrast, estimated an average cost of only $13,000 for annual maintenance of the consumer tool. One respondent elaborated that, “maintaining the tool would take a dedicated department.” As codes are updated and new procedures are introduced, the tool would have to be kept up to date.

The Negotiated Rate File similarly was seen as much more costly to implement (again by a factor of around twenty) than estimated by the Departments. Carriers estimated set-up costs surpassing $2 million, on average. While not quantifiable, some respondents indicated that certain aspects of this portion of the Proposed Rule are not feasible. Specifically, they noted that negotiated rates for performance-based (quality-adjusted) and experience-based (risk-adjusted) contracts can only be calculated ex-post and would not necessarily reflect rates going forward. While beyond the scope of this paper, carriers also expressed concerns that went beyond operational costs. In particular, some carriers expressed substantial concern about the confidentiality of the information that would be required to be made public in this file as well as concerns about the potential complications such disclosure poses for their negotiations with providers.

There was less agreement and understanding about the costs and complexities of generating the rate files, given that these are entirely new ideas. Estimates for setting up the Negotiated Rate File (approximately $2.14 million) and setting up the Allowed Amount File (approximately $1.07 million), both significantly exceeded the Departments' estimates of $107,905 to set up the Negotiated Rate File and $117,757 to set up the Allowed Amount File. Carriers interviewed estimated the annual costs of maintaining the Negotiated Rate File and the Allowed Amount File at $467,000 and $643,000, respectively. Both of these maintenance estimates surpassed the Departments' set-up estimates for the same files. Given the unprecedented requirement and lack of carrier experience, it was difficult for carriers to estimate these potential costs.

For the Allowed Amount File, some respondents expressed concerns about maintaining HIPAA protections because of the small numbers of claims associated with particular services and out-of-network providers. Others expressed that most carrier members used in-network services, and, thus, there would be "holes" in the file generated using historical data from a narrow period of time. Another carrier mentioned that, "it's difficult to get demographic/directory information from OON providers."

Given the short window of commenting on the proposed regulation, we were not able to estimate the impact of all of the potential implications regarding the public release of negotiated prices or additional costs to carriers beyond the operational costs of setting up these files. These implications could be significant, including the potential for increased payment rates to providers, increasing healthcare costs. Such implications merit further analysis.

VI. CONCLUSIONS

Through a targeted interview process with 18 carriers that are generally representative of the private health insurance industry in the U.S., we evaluated the feasibility and operational cost imposed on carriers of implementing the TCR transparency requirements recently proposed by the Departments. Importantly, we did not consider the broader economic and financial implications of disclosing payment rates that have been negotiated between hospitals and health care providers, and insurance carriers. That analysis is beyond the scope of this paper, but could have a significant impact on health care cost and quality.

We found that while most carriers are still working to digest the impact these regulations will have on their businesses, we did obtain high-level estimates of the cost of implementing the regulation's primary requirements from a meaningful number of respondents. The responses cover a wide range that reflect the differences in the carriers themselves, their different states of readiness for developing tools called for in the regulations, and different perceptions and understanding of what the regulations will require.

Despite the wide range of estimates, the clearest result we have is that the interview respondents view the proposed regulations as far more costly and disruptive than is reflected in the Departments' published estimates. A consistent theme was that carriers are steadily moving in the direction of providing more information and tools to their members to increase transparency about the cost of care based on customer experience research. There is concern that the regulations, as written, would not only impose substantial cost, but that they would also most likely result in tools that are less useful to consumers.

Our primary observations are as follows:

- The Consumer Search Tool was seen as a much more costly and disruptive element to implement than was estimated by the Departments. Based on interviews, there is a range of potential costs for implementing the Consumer Search Tool – all of which are significantly higher than the agencies' estimates. Although most of the carriers we spoke with have an existing consumer-facing tool meeting many of the required elements of the TCR, several carriers expressed severe concern about the cost and feasibility of implementing the requirements as written. Multiple respondents indicated that the requirements may necessitate a complete rebuild of their consumer tool. Key concerns include:
    - As written, the TCR references providing pre-service estimates of *all* services (discrete or bundled) that would be covered. This requires a carrier to essentially engage in a mock claim adjudication which can be highly complex depending on the goods or services involved.
    - This requirement also requires costly and complex integration of benefits that are not uniformly maintained within existing systems. Pharmacy benefits, benefits provided through third-party administrators, medical management requirements, visit limits and allowed out-of-network benefits were key elements of concern.
    - There seems to be a core set of functions for a core set of services that the majority of respondents report having currently. These include the ability for members to: (1 learn about their OOP costs for some items and services; (2 search for items and services by provider and by descriptive terms; and (3 filter and sort by geography, OOP costs and distance. Currently, the average number of items and services for which OOP costs are provided is 1,011, with a maximum of approximately 1,600. The carriers we interviewed typically focus on "shoppable" and commonly utilized items and services (or in some cases, procedures and bundles).
    - The requirement does not appear to recognize the unavoidable uncertainty in defining and pre-determining the precise services that may be provided in a given care setting. This uncertainty greatly complicates providing precise estimates of cost in many settings. One knee replacement, or one child birth, will not be the same as others, for example. It would be difficult to communicate to customers what the cost of their precise experience would be in any matter in which there is a

need for provider choice and adjustment to medical circumstances that cannot be known in advance. Some respondents indicated that inputs from providers such as diagnosis codes may be necessary to reflect the degree of precision specified in the rules.

- Multiple respondents indicated that they have existing business strategies focused on increasing cost transparency for members in a way that enhances the consumer experience. They have concerns that certain TCR requirements are inconsistent with those strategies and would require changes in customer service priorities that they see as detrimental to care and the customer experience.

- Carriers viewed the Negotiated Rate File as much more costly to implement (by a factor of approximately twenty) than estimated by the Departments. Carriers estimated set-up costs surpassing $2 million, on average. While not quantifiable, some respondents indicated that certain aspects of this portion of the Proposed Rule are not feasible. Specifically, they noted that negotiated rates for performance based (quality-adjusted) and experience based (risk-adjusted) contracts can only be calculated ex-post and would not necessarily reflect rates going forward.

- Generally, we found that interview respondents shared consistent concerns about the high cost and significant complexity associated with producing an Out-of-Network Allowed Amount File. While no carrier had carefully evaluated the cost of publishing such a file, carriers estimated set-up costs of over $1 million (about nine times higher than estimated by the Departments). In addition, some respondents expressed concerns about maintaining HIPAA protections because of the small numbers of claims associated with particular services and out-of-network providers.

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Ribbon's feedback and questions:

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Our understanding of the purpose of this data: Lay the groundwork for consumer-transparency.

Our overall assumption is that the intent of this data is to begin to enable *consumers* (via consumer-facing tools) to understand how much they might need to pay for medical care (knowing that the burden for payment is split between the consumer and the payer according to their plan benefits).

We understand that consumers may not access this data in 2022 directly, but it could readily feed into a diverse digital health tech space that ultimately reaches consumers. And we understand the data to lay the groundwork for the 2023 requirement for consumer-facing self service tools.

This "purpose" would be in contrast, for example, to data that was meant to illuminate / support research on the payment transactions / models between payers and providers (which are numerous). This distinction in the "purpose of this data" is important when we get to things like bundled / capitated payments.

Feedback area 1: Ensuring consumers can identify their plan in these data files.

- Overarching question: We know that plan names can be generic with many customizations within them - and marketing to members can be unclear. Doe the IDs listed here enable a member to identify their plan in these files / schemas?
    - Would creating a field for "Plan name as visible / marketed to member" be useful?
- Plan ID should be a required field for all schemas (currently it seems it is required in some but not others)

Feedback area 2: Ensuring the files can be easily found on payer sites

- Could CMS host a table with a link to where each plan is storing their information?
- Could CMS specify where in the payer's site the fill is placed?

Feedback area 3: Clarifying when and how to use bundled and capitated payment options - orienting towards the consumer's potential payment responsibility

- Overarching question - CMS should clarify to payers that the bundle and capitation fields should be used when these arrangements impact billing to the member
- Capitation: Our understanding of how most capitation arrangements work is that payers / providers bill members "as usual" (FFS) and then on a monthly / periodic basis true up relative to the capitation amount in a way that has no immediate impact to the member (in theory any savings are passed down through lower premiums / richer benefits next year etc.)

    - Under these arrangements, since the member is still billed the same way (e.g. the FFS prices will still apply to the member's deductible, Out-of-pocket maximum etc.) **the payer should still report their underlying FFS negotiated rates with providers.**
- Bundles: Our understanding is that bundles split into two cases:
    - Bundles that are invisible to the member (payers and providers "true-up" retrospectively) - **in this circumstance the payer should still report their underlying FFS negotiated rate**
    - Bundles are visible to the member (either processed in real time, or a transaction occurs retrospectively with the member) - this is common for maternity.
        - **In this circumstance, the payer should report the bundled rate that will ultimately be experienced by the member**
        - In this scenario, a few attributes are critical:
            - Anchor procedures:
                - What are the anchor procedures that would trigger a bundled arrangement in the payer's claims system? (e.g. this would be a list of CPT codes for a knee replacement surgery, say)
                - Which providers is the negotiated bundled payment rate with? There should be an option for "All providers in network"
            - Auxiliary procedures included in the bundle, in some time window:
                - Time window: During what window around the surgery is the payer's system "grouping" claims related to the anchor surgery (e.g. the imaging before the surgery, the anesthesia during the IP stay, etc.)
                - List of auxiliary procedure codes (CPT, drug, etc.)
                - Note: there could be multiple time windows for different aspects of the bundle - e.g. a different window for post-operative PT vs. for imaging procedures

    -

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March 1, 2021

William Parham, Director
CMS Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development / Paperwork Reduction
Attention: **CMS-10715 / OMB Control No. 0938-1372**
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Submitted electronically via http://www.regulations.gov

Re: Part A Transparency in Coverage Model Notice and Data Forms (CMS-10715 / OMB control number 0938-1372)

Dear Mr. Parham,

UPMC Health Plan and the integrated companies of the UPMC Insurance Services Division (collectively, "UPMC") are pleased to submit the following comments in response to the Paperwork Reduction Act solicitation regarding Part A Transparency in Coverage Model Notice and Data Forms, as published in the federal register on December 30, 2020.

UPMC offers a wide range of commercial group and individual, Medicare, Medicaid, CHIP, and ancillary coverage products to consumers in Pennsylvania, West Virginia, and Ohio. Since beginning operations in 1996, UPMC has been recognized for its dedication to quality and the provision of outstanding customer service across its product lines, which collectively provide commercial or government programs coverage to almost 4 million members. UPMC has offered consumers a variety of coverage options as a QHP issuer since the launch of the Marketplace in 2014, and currently provides coverage to over 100,000 Marketplace enrollees. In several Pennsylvania counties, UPMC is the only QHP issuer currently offering a product through the Marketplace.

We thank CMS (the "Agency") and your office for affording issuers and other stakeholders an additional opportunity to comment on the model notice and data submission forms drafted pursuant to the Transparency in Coverage Final Rule (85 FR 72158). UPMC supports providing all individuals with comprehensive, easily accessible information regarding the terms of their health plan coverage. It is with this support in mind that we respectfully offer the following comments on

the proposed scope and format of data disclosure as well as selected portions of the Model Notice.

Scope of Data Disclosure

UPMC supports the Agency's goal to provide enrollees with accurate, actionable price information concerning their cost-sharing liability and believes that maintaining an internet-based self-service tool is an efficient delivery method by which to accomplish this end. UPMC currently offers our commercial enrollees, including those enrolled in both group and individual market coverage, access to such a personalized tool. Specifically, our price transparency tool allows enrollees to estimate the out-of-pocket cost of approximately 350 different health care procedures and services, including elective outpatient surgery, inpatient surgical services, inpatient non-surgical services, physician services, outpatient laboratory services, and radiology services. We also offer our members access to a separate pharmacy tool that is capable of estimating out-of-pocket costs for prescription drugs, with relevant pricing information on generics, preferred brands and non-preferred brands.

These pricing tools provide information on estimated enrollee cost-sharing liability, including deductibles, coinsurance, copayments, cost-sharing reductions, and accumulated amounts incurred to date. The tools also indicate our negotiated rate with in-network providers for specific items and services. This same cost information can also be obtained by calling our Member Services team.

Although UPMC supports transparency and arming enrollees with information they need to make informed healthcare choices, we are concerned that the separate requirement to publish a machine readable file of negotiated rates for all covered health care items may be administratively burdensome and offer very limited benefit, notwithstanding the additional time and financial investment such a disclosure mechanism would also require.

Rather, we support an approach that would limit any list of covered items and services to those that are most widely utilized and/or sought by consumers (i.e., shoppable services). This hybrid approach will ensure that enrollees have access to actionable cost information and relative pricing information for services that are commonly subject to comparison shopping, without risking inundation by non-relevant data that is not critical to assessment of their own financial liability.

A similar approach was partially adopted in the recent CY 2020 OPPS Policy Changes: Hospital Price Transparency Requirements final rule (the "2020 OPPS rule"), which finalized requirements for making public discounted cash prices, payer-specific negotiated charges, and de-identified minimum and maximum negotiated charges for at least 300 'shoppable' services (70 CMS-specified and 230 hospital-selected) that are displayed and packaged in a consumer-friendly manner. While we fully support providing health care consumers with enough information to facilitate informed decision-making, more information is not inherently better or beneficial unless it provides actionable insights, and in many cases delivering additional information without a clear purpose or utility may actually be counterproductive to the facilitation of rational consumer decisions. In most common health care delivery scenarios, the negotiated price of an item or service from a single provider is only relevant insofar as it relates to the calculation of a member's cost-sharing liability. Additionally, many uncommon or complex procedures are not good candidates for uniform, "single scenario" price estimates because the accuracy thereof is highly dependent upon a patient's unique clinical characteristics. Including such services in the proposed machine readable files without producing misleading or inaccurate results among a diversity of information intermediaries (e.g., third party app developers) will require significant additional time and financial investment from plans without increasing overall utility for the majority of consumers. Given the foregoing concerns, we believe that a limited list of commonly searched shoppable services, similar to that adopted in the 2020 OPPS rule, will be more effective in providing consumers with meaningful pricing information. Such an approach would also allow the Agency and issuers an opportunity to place appropriate emphasis on consumer-facing tools, like those called for in the "No Surprises Act," which are likely to offer substantially more utility and practical support for consumer decision-making.

Model Notice: Key Terms

The model notice includes definitions for several "Key Terms" designed to aide consumers in better understanding the terminology that is necessarily a component of their requested cost estimate. While we agree that this section represents an important part of the notice for consumers, we question that model notice placement of this information in front of the "Important Information" section. Our experience in serving millions of members across a diversity of

coverage products suggests that many consumers will review the first page of information provided, but are likely to give a limited or only cursory review of the subsequent informational pages before focusing on the cost estimate itself. Moreover, in the absence of obvious context (e.g., definitions printed on a form in which they are used), consumers have a natural tendency to focus on narrative information rather than segmented technical material like the Key Terms; the proposed format thereby limits the practical value of the otherwise vital front page real estate currently dedicated to the Key Terms. While we appreciate the Agency's allowance for plan modification of the model notice, we expect that many coverage providers will, at least initially, adopt the notice largely as written; as such, the utility of the model as written is critical to promoting consumer understanding of newly available cost estimate information. Critical to this understanding is an emphasis on what the estimate does and does not actually provide, particularly given the likelihood of consumers' direct reliance on this information for significant decision-making regarding their use of the health care system. In light of these considerations, we would encourage the Agency to reorder the sections of the model notice and dedicate Page 1 to the "Important Information" section.

Allowed Amount

The proposed definition for this term limits its use to out-of-network providers. In part because Explanation of Benefit (EOB) are typically uniform in their structure, we believe that this term is equally applicable to care scenarios with all providers regardless of their network or out-of-network status. Additionally, we question whether it is truly accurate to describe this term as the "maximum amount" applicable to an out-of-network provider. Payments for out-of-network claims are often negotiated between plans and providers; while the Allowed Amount represents the plan's intended level of payment, it is often the case that plans ultimately pay more than this amount to prevent providers from balance billing patients. Implementation of the No Surprises Act and the associated baseball-style arbitration process clearly demonstrates that the Allowed Amount as determined by a plan is not in fact the maximum amount a plan may ultimately pay for a service. Based on these complexities, we would encourage the Agency to consider the following definition for Allowed Amount on the model notice:

> *The **Allowed Amount** is the maximum amount that your health plan will normally pay for a covered item or service. Your plan may be required to*

pay more than this amount for services from an out-of-network provider. Even if your plan has to pay more, your Cost Sharing [for emergency services] will be based on the Allowed Amount.

Cost Sharing

The proposed definition for this term includes a section with instructions to include certain additional statements "if balance billing is permitted under state law." While the prescribed additional statements do include some information about balance billing, they also convey consumer responsibility for other costs like premiums and claims for non-covered services. We believe that this information is universally applicable and should therefore be included regardless of state balance billing requirements. We recommend that the Agency clarify the scope of its instructions in this definition to apply only to those elements that are truly specific to balance billing, and offer the following for the Agency's consideration:

> ***Cost Sharing*** *is your share of costs for a covered item or service that you must pay (sometimes called "out-of-pocket costs"). Some examples of cost sharing are deductibles, coinsurance, and copayments. This term does not include other costs you may be responsible for, such as premiums, [include this if balance billing is permitted under state law: balance-billed amounts for out-of-network providers,] or the cost of items or services not covered by your health plan.*

Accumulated Amount

This term represents one of the most complex aspects of consumer information about their health plan coverage because understanding its limitations requires an appreciation for the mechanics of claim submission and processing. Specifically, it is often unclear to members why their plan accumulators don't reflect care that they have recently received or copayments that they have recently paid; in some cases, out-of-network providers in particular may take several weeks or even months to submit a claim, which is not obvious or intuitive for consumers when examining the status of their plan coverage. As such, while we do not disagree with the content of the proposed definition, we encourage the Agency to consider the addition of information that we believe furthers consumer understanding:

*An **Accumulated Amount** is the amount of financial responsibility you have already incurred at the time a request for cost-sharing information is made, with respect to a deductible or out-of-pocket limit. This amount may not include recent cost sharing until your provider has submitted a claim for payment from your plan. This usually happens quickly but can sometimes take several weeks, particularly for out-of-network providers.*

Model Notice: Important Information

As more fully explained herein (*see* Key Terms), we encourage the Agency to consider emphasizing this section by placing it on Page 1 of the model notice. While we support the inclusion of comprehensive information on all of the sections identified in the model notice, we believe that the Important Information section includes details on the limitations and uses of the Cost Estimate that are fundamentally critical to consumer understanding of the information that is being provided. We also offer the following comments on specific sections of the Important Information section.

Item 5 (Preventive Services)

We agree with the Agency's inclusion of information regarding billing for preventive services. These services are a common source of consumer confusion or misunderstanding as members often assume that their health plan has primary authority to make determinations regarding the application of cost-sharing. Patients who believe they are receiving a preventive service are understandably frustrated when that service is ultimately billed as a diagnostic or interventional service that is then associated with cost sharing. To further consumer understanding of the responsibility for determinations regarding the coding of a preventive service, we encourage the Agency to consider adopting the following explanation for this section:

An in-network item or service may not be subject to cost sharing if it is billed as a preventive service. Your health care provider is responsible for telling your plan whether the item or service you receive is preventive.

Model Notice: Prerequisites

We support the inclusion of this section regarding the need for satisfaction of certain prerequisite conditions before coverage will be provided for a particular

item or service. We also appreciate the Agency's flexibility in asking plans to include this section only when applicable to a component of the requested Cost Estimate. However, we believe that there are two important modifications necessary to ensure that consumers fully understand the application of prerequisites under their plan.

The notice instructions call for inclusion of prerequisite information only if an item or service component of the requested Cost Estimate is subject to the prerequisite in question. While this conditional requirement is readily applied to care from in-network providers, it is often the case that many or all non-emergency services require authorization before coverage will be provided for out-of-network providers. Accordingly, we encourage the Agency to consider adding the following optional statement to Subsection A of the Prerequisites section:

> *[Most/All] non-emergency out-of-network services require prior authorization even if authorization is not required for the same in-network service.*

In addition, the Prior Authorization narrative notes that a plan "may impose additional costs" if the required authorization is not obtained. We are concerned that this statement implies coverage will be provided for non-authorized services even when authorization is required and that there may merely be some additional cost sharing involved. However, in many cases a failure to obtain a required authorization can mean that the item or service in question is not a covered service under the plan as, in the absence of authorization, associated claims may deny due to the inability to determine whether the provided service met the clinical criteria necessary for coverage. As such, we encourage the Agency to incorporate the following adjustments to the referenced statement in Subsection A:

> *Your health plan may impose additional costs* ***or deny coverage*** *if you or your provider do not submit this item or service for [SELECT PLAN TERM: prior authorization, preauthorization, prior approval or precertification] before the item or service is provided.*

We thank CMS for its commitment to supporting informed health care consumer decision-making and promoting a vibrant, competitive health care market that

encourages plans to offer consumers a variety of affordable, comprehensive coverage options. We appreciate your consideration of these comments and look forward to continued collaboration in the future.

Respectfully Submitted,

Caleb B. Wallace, Esq., MPH
Vice President, Health Policy & Regulatory Affairs
Assistant Counsel
UPMC Health Plan

March 1, 2021

Submitted electronically via federal eRulemaking Portal: http://www.regulations.gov

Mr. William N. Parham, III
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier CMS-10715
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Baltimore, Maryland 21244–1850

Re: Transparency in Coverage (CMS-10715)

Dear Mr. Parham:

On December 30, 2020, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register*[1] an information collection request (ICR) regarding implementation of the Transparency in Coverage final rule, as required by the Paperwork Reduction Act (PRA).[2] Materials were posted for public viewing on January 13, 2021.[3] In the final rule authorizing this ICR, issuers will create an online enrollee self-service tool (ESST) that will return estimated cost sharing for covered items and services beginning in 2023 for a select set of services and in 2024 for drugs and all other items and services. In addition, the final rule requires issuers to disclose negotiated rates and historical net prices for drugs at the National Drug Code (NDC) level for each applicable plan, beginning in 2022, through the release of publicly-available machine-readable files (MRFs).

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 through the Exchanges established by the Affordable Care Act (ACA). Our members work closely with plans and issuers to secure lower costs for prescription drugs and achieve better health outcomes.

While PCMA supports consumer-focused transparency, we have serious concerns with several aspects of CMS's approach as described in the Transparency in Coverage final rule. We raised many of these issues in response to the proposed rule issued in November 2019, in which we objected to the release of negotiated payment rate data in MRFs as creating little consumer benefit at a great expense.[4] We also recently responded to the 2022 Notice of Benefits and Parameters proposed rule earlier this year, highlighting new concerns based on the final rule's language. The healthcare industry has learned, through the implementation of the Hospital Price Transparency rule this year, that negotiated rate disclosure in a highly complex pricing environment leads to an inconsistent

[1] 85 Fed. Reg. 86567 (December 30, 2020).
[2] 85 Fed. Reg. 72158 (November 12, 2020).
[3] Documents are posted online at https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10715.
[4] Available at https://downloads.regulations.gov/CMS-2020-0151-0162/attachment_1.pdf.

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implementation and problematic interpretations by market participants. This does not serve the goal of furthering a "shoppable experience" in healthcare and may create further confusion for consumers. **In short, PCMA recommends CMS not implement the MRF requirement until 2023 at the earliest.**

Beyond this necessary delay, both the MRF and the ESST requirements require additional notice-and-comment rulemaking to address regulatory gaps in the final rule regarding historical net price and other new definitions. CMS also must conduct a better accounting of the costs and time burdens imposed on the public, and then reconsider whether the costs outweigh the purported benefits.

Our comments are structured as follows:

I. General comments regarding the reporting of historical net prices for prescription drugs as part of the MRF
II. Response to the Supporting Statement's time and cost burden estimates
III. Responses to specific data elements in Appendices 2, 3, and 4

* * * * *

I. CMS Needs to Undertake Additional Notice-and-Comment Rulemaking

The Transparency in Coverage final rule imposes broad and expensive burdens on health plans and group health insurance issuers. We raise two substantive areas that CMS should address regarding implementation of this final rule, which we believe will require a delay of the delivery of MRFs to at least January 1, 2023, and considerations for delaying the enrollee self-service tools as necessary.

A. Historical net price

The final rule's provision regarding the inclusion of historical net prices for prescription drugs in the MRF was not included in the proposed rule. As a result of this absence of notice, specific feedback stakeholders might have otherwise provided was not accounted for in the final rule. Had the public been given notice regarding the potential inclusion of this data element, PCMA would have commented in opposition for several reasons, set forth below.

The disclosure of historical net prices will lead to increased costs for prescription drugs. Through both tacit collusion by drug manufacturers and an undue focus on unit pricing, requiring public reporting of this novel data element will increase costs for affected health plans, and ultimately consumers. When manufacturers have insight into the minimum level of discounts needed to achieve formulary coverage or preferred status, they begin to pull back on more aggressive offers, and net prices rise as a result.[5] CMS itself has acknowledged that the release of commercially or financially sensitive data to the public could negatively impact the ability to negotiate for better prices, and ultimately affect overall healthcare costs.[6]

[5] See for example CBO, "Potential Effects of Disclosing Price Rebates on the Medicare Drug Benefit." Available at https://www.cbo.gov/system/files/2018-10/03-12-drug-rebates.pdf and FTC. "Price transparency or TMI?" Available at https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi.
[6] 73 Fed. Reg. 30668 (May 28, 2008).

As the Departments acknowledged in the economic analysis accompanying the proposed rule,[7] such disclosures are likely to yield an increase in health care service prices. In response to an earlier HHS proposal, we established that disclosing net drug prices would cause net drug prices to rise, as a result of "tacit collusion."[8] In that proposed rule, HHS's economic analysis assumed net drug prices would increase by 15%.[9] The Departments should expect the same level of net price increases under this program.

To further describe the long-term spillover effects, we quote the Congressional Budget Office (CBO)'s landmark 2007 paper, which laid out the advantages and disadvantages of price transparency in health care. In it, CBO writes:

> "[I]ncreasing transparency in such markets could lead to higher, rather than lower, prices. In markets where only a small number of firms operate, increased transparency would make it easier for those firms to observe the prices charged by their rivals, which could lead to reduced competition between them. In health care, reduced competition might result if more transparent pricing revealed the prices negotiated between insurers and providers, especially in concentrated markets."[10]

Further, because the purchase of certain health care services is often mandatory (e.g., the federal Essential Health Benefits requirement that issuers cover prescription drugs), transparency can be doubly damaging, according to many respected health economists, because there are so few data points that a supplier needs to learn in order to gain the upper hand.[11,12] More succinctly, the Federal Trade Commission (FTC) has stated that:

> "[I]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors …then tacit collusion among manufacturers is more feasible… Whenever competitors know the actual prices charged by other firms, tacit collusion–and thus higher prices–may be more likely."[13]

In general, increased cost transparency reduces negotiation leverage, which would result in higher overall prescription drug spending, through higher net costs. With enhanced price transparency, manufacturers will therefore be able to better determine their competitors' offers. This will result in tacit collusion and eliminate incentives for manufacturers to negotiate the lowest possible discounts, in

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[7] 84 Fed. Reg. 65457 (November 27, 2019), at 65492.
[8] See pages 29-34 of PCMA's response to the HHS OIG Rebate Safe Harbor Proposed Rule here: https://www.regulations.gov/contentStreamer?documentId=HHSIG-2019-0001-19773&attachmentNumber=1&contentType=pdf.
[9] 84 Fed. Reg. 2340. (February 6, 2019), at 2356.
[10] CBO, "Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals," (June 2008), page 4. Available at https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf.
[11] See Danson, PM. "Pharmacy Benefit Management: Are Reporting Requirements Pro or AntiCompetitive?" Available at https://faculty.wharton.upenn.edu/wp-content/uploads/2015/10/Danzon-PBM-IJEB-2-25-15-formatted-4-1-15-(002).pdf.
[12] Alison Kodjack, "It Will Take More Than Transparency To Reduce Drug Prices, Economists Say." (March 22, 2019). Available at https://www.npr.org/sections/health-shots/2019/03/22/705469296/it-will-take-more-than-transparency-to-reduce-drug-prices-economists-say.
[13] U.S. FTC, Letter to Assembly Member Greg Aghazarian, 2004. Available at https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf.

order to protect market share. They will know exactly how much discount would have been required to "win" on contracts they have lost, or how much smaller a price concession they could have yielded on the contracts they won. While CMS may justify the rule by embracing a short-term reset of pricing structures to re-align the current incentives, FTC's and CBO's work instead cautions that such transparency will have lasting effects and changes the nature of negotiations altogether.

Unit pricing sends the wrong signals to market participants. The disclosure of historical net prices will also lead purchasers of group health insurance to focus on the unit prices of drugs paid by their contracted issuers and PBMs, rather than the value of the mix of drugs covered and dispensed. For example, an issuer's higher net price on certain brand drugs may not mean higher *spending* if they are more effective at moving enrollees to lower-cost therapeutic alternatives, including generics. While the overall health care system slowly transitions to value-based approaches, a fixation on unit prices would move to undermine this approach.

Historical net price does not follow from the authorizing statute. Had historical net price been proposed for inclusion in the MRF, we would have objected to its inclusion because prescription drug pricing data is not on ACA section 1311(e)(3)'s enumerated list of items to be reported to the Secretary (nor, as codified by CMS at 45 C.F.R. 156.220). In the final rule, CMS justifies several of the required data elements through the catch-all item at the end of the list ("Other information as determined appropriate by the Secretary"). While Congress very clearly gave the Secretary the ability to require the reporting of "other information" *similar to that specifically enumerated in the statute*, it did not grant the Secretary the ability to require reporting of information outside-the-scope or dissimilar to those items already listed. As we argued in our comments to the proposed rule,[14] a general term that follows an enumerated list of more specific terms should be interpreted to cover only "matters similar to those specified."[15] The catch-all item does not grant the Secretary the ability to require reporting of information outside the scope or dissimilar to those items already listed.

Given our support for other aspects of the final rule authorized by section 1311(e)(3) (namely, the concept of ESST), it is clearly *not* PCMA's position that the Departments' lack the authority to require the disclosure of *any* information that is not specifically identified in section 1311. Rather, we believe it is incumbent upon the agencies to justify such disclosures within the statutory framework. As a result, the Departments lack authority to require the disclosure or reporting of information outside the scope of section 1311, which would include confidential and proprietary information in the form of prescription drug net prices as currently constituted.

Beyond the statute, historical net price is not supported by *this ICR.* CMS justifies this ICR by implying that consumers will be better able to shop for health care items and services most efficiently.[16] However, as CMS is plainly aware, net prescription drug prices are not charged to members. This requirement violates the spirit of the data collection and Congress' own intent in establishing the transparency provision. Cost-sharing for prescription drugs, instead, is based upon the negotiated rates paid to the pharmacy, which are also subject to disclosure under this ICR, and which we do not oppose, or flat dollar copayments, unrelated to the specific list, negotiated, or net price of a drug. While

[14] Available at https://downloads.regulations.gov/CMS-2019-0163-19236/attachment_1.pdf.
[15] *Gooch v. United States*, 297 U.S. 124, 128 (1936). *Accord Hall St. Assocs., L.L.C. v. Mattel*, Inc., 552 U.S. 576, 586 (2008) ("Under that rule [of *ejusdem generis*], when a statute sets out a series of specific items ending with a general term, that general term is confined to covering subjects comparable to the specifics it follows.").
[16] See Supporting Statement – Part A Transparency in Coverage, page 3: "With better information, consumers may be able to shop for health care items and services more efficiently, and potentially create more competition and demand for lower prices."

the agency justifies this disclosure in terms of consumer benefit, it fails to articulate how the disclosure of historical net price provides any real benefit to consumers.

Better approaches to drug price transparency exists. Had CMS proposed this concept officially, it would have received comments indicating that there are more effective approaches to disclosing net prices. These include lagged reporting and sufficient aggregation. Since the prescription drug market changes fairly rapidly (meaning, new drugs are approved or lose patent exclusivity, increasing competition among brands and with generics), lagged data in part mutes some of the anticompetitive effect of the disclosure. The discount needed to secure preferred formulary position three years prior may be unrelated to the composition of that market, in the current plan year. However, the release of the lagged data allows purchasers of group health coverage to compare their results to plans offered by other issuers. While we acknowledge the final rule allows for aggregation in the case of low volume drugs (where there are fewer than 21 patient claims paid by the issuer), the disclosure of drug-specific net prices does not improve consumer or health plan purchaser comparisons. Aggregation by therapeutic class or disease state can give a clearer picture as to the success of an issuer and its PBM in controlling costs for hard-to-treat populations.

B. Other substantive gaps in the final rule

The final rule also fails to address all necessary definitions and descriptions that issuers will need in order to comply. Through additional rulemaking, CMS should further define "items and services"[17] and "accumulated amounts."[18] For the ESST, our PBM members also have questions regarding the level of detail that must be returned on a search.[19] These questions are not addressed in the final rule or in this ICR. Nor are conflicts created by new mental health parity reporting requirements[20] and price disclosures enacted by Congress at the end of 2020, which followed the publication of this final rule and occurred at the same time as the creation of these forms. (We discuss legislative requirements for transparency in the next section.)

***PCMA Recommendation*: CMS should not collect historical net price under this ICR. CMS should issue new notice-and-comment rulemaking to address the many open questions created by the Transparency in Coverage final rule, including to determine whether it should collect historical net prices at all.**

II. CMS's Time and Cost Burdens are Inadequate and Conflict with Other Clear Priorities

CMS's cost estimates are incomplete. The proposed rule, final rule, and this ICR all acknowledge significant costs that the MRF and ESST would impose upon health insurance issuers and their contracted partners such as PBMs. The ICR assesses $1 billion in costs for 2021 (related to MRF), $5.4 billion in 2022 (MRF and ESST), and $3.5 billion in 2023 (MRF and ESST). These costs are consequential and not fully explored by CMS in the proposed or final rules. For example, the identified employees would also be managing external IT vendors and interacting with contracted entities such

[17] For example, should plans include in the prescription drug file physician administration services for brown-bagged (pharmacy-paid) drugs that are not paid incident-to a physician's service?
[18] For example, how should plans report progress toward a maximum annual dose of a prescription drug, with regard to "cumulative treatment limitations"? Using the prescribed amount or the dispensed amount?
[19] For example, how many in-network and out-of-network providers must be returned? Can it be limited to a number, or must it be every single provider?
[20] See https://www.natlawreview.com/article/consolidated-appropriations-act-underscores-mental-health-parity-compliance for a description. HHS will need to issue guidance or rulemaking on this topic by June 2022, and could create a conflict with the ESST results for mental health services.

as PBMs, who would bear their own development, data storage and reporting costs, and are not accounted for in CMS's estimates. Also, PBMs are just one of many third-party administrators an issuer may employ. CMS's wage table and hours estimates also ignore any involvement by attorneys and executives, who assuredly will be involved given the confidential and proprietary nature of much of this data, and whose involvement would further increase the costs. CMS should acknowledge that these costs will be incorporated into insurance premiums paid by employers and employees, individuals, and taxpayers through Advanced Premium Tax Credits, and reconsider its approach.

The burden of the files will fall on a public unable to benefit from them. CMS has underestimated the number of unique files issuers may need to create. From a privacy standpoint, for historical net prices for prescription drugs, there is likely to be a lot of suppressed data. Further, the interested public likely cannot usefully aggregate and make sense of these files full of suppressed data points. Aggregated data like that now required by Congress would seemingly better meet CMS's needs.

There is limited cost-efficiency in translating from Medicare Part D processes. We believe some of the estimates are generated based on the idea that much of this already occurs within the Medicare program, with the Medicare Plan Finder and Direct and Indirect Remuneration reporting. However, the level of variation and complexity in commercial PBM plan design, formulary and therefore group level pricing, is significantly higher than that of Medicare plans which are highly regulated and relatively consistent. To illustrate this point, where Medicare may have a dozen pricing variances within a single PBM, commercial pricing structures have thousands. To achieve the level of granularity required for the pharmacy MRF for negotiated price, and account for the multiple contributing inputs including but not limited to network tiering, formulary placement, and daily drug price changes, CMS is essentially requiring the development of a secondary adjudication system for billions of records. The development, data storage and aggregation resources required will exponentially inflate costs while providing limited useable information, as noted above. Including negotiated rates and historical net price data in a single file creates an additional administrative burden to PBMs. These are two distinct, complex data sets. Combining them into one file prevents PBMs from leveraging existing functionality that has been built to separately support Medicare pricing files and historical Prescription Drug Event (PDE) data.

CMS should pause this ICR until the COVID PHE has ended. CMS should also acknowledge that the time it spends on implementing this regulation in 2021, and the time it asks the public to spend, is time that cannot be used by plans and federal officials alike to respond to the COVID-19 public health emergency (PHE). We know that CMS staff have been working tirelessly since last winter to address ways that its programs can help providers respond and enrollees access tests, treatments, and now vaccines. As CMS itself knows, health insurance issuers and contracted entities like PBMs have been doing the same. Dedicating staff (CMS or private sector) to come into compliance with this regulation means likely pulling them off of critical pandemic-related, response-related work. CMS should consider delaying the implementation of this regulation and ICR (and any others that are not "mission critical") until the PHE has ended.[21]

Congress and CMS are asking for similar data through other means. The cost estimate discussion above does not account for the overlap in systems development that is underway and planned. As CMS is aware, it currently also has an ICR open regarding PBM transparency. While PCMA continues to work with CMS to fine-tune the required data elements and timing, the very same staff at CMS and within PBMs would be pulled away to work on MRF on a more aggressive timeline. The Consolidated Appropriations Act on December 27, 2020, also imposes new reporting requirements on health insurance issuers regarding prescription drugs that will require full notice-and-comment rulemaking,

[21] In March 2020, the White House directed all federal agencies to make such considerations. See https://www.whitehouse.gov/wp-content/uploads/2020/03/M-20-16.pdf.

by HHS, U.S. Department of Labor, and U.S. Department of Treasury by June 2022.[22] Finally, plans and issuers are spending innumerable hours and dollars building up their IT systems in order to comply with the several health data exchange and interoperability rules issued by CMS since 2019.[23]

In fact, the PBM transparency example highlights exactly why 2022 is far too soon to implement MRF, notwithstanding the clear need to prioritize the nation's COVID response. This other, narrowed, program was first outlined through a PRA filing in January 2020. It will not begin collecting data until 2022 at the *earliest*.[24] Two years is a bare minimum to stand up a new reporting paradigm.

***PCMA Recommendation*: CMS should delay the requirement to publish the three MRFs until at least 2023, to align with other ongoing transparency efforts and address open issues.**

III. Responses to Specific Data Elements in the Appendices

Below we provide feedback on specific data elements within each Appendix. Our feedback does not endorse the collection of such data, to the extent we argue against it in the paragraphs above. Nor does our feedback concede that such data can be feasibly reported beginning January 1, 2022. Rather, we provide these responses in an effort to move CMS's efforts along with the explicit acknowledgment that doing so is only feasible if the MRF is delayed to January 1, 2023 or later.

Before discussing these data elements, we wish first to comment on CMS's use of the Github open source platform for providing technical guidance, in place of formal guidance or other subregulatory issuances. While we understand that the Github documentation is intended to provide examples to issuers as they develop their systems, there does not seem to be a mechanism to notify issuers of new information being available, or of changes made to previous versions. We appreciate that CMS is testing out new ways to provide information and interpretation in closer to real time but would benefit from a clearer description of the platform's intended use and the binding (or non-binding) nature of the information provided within it.

A. Data Elements Used in Several Files

- Plan identifiers
  - Currently the MRFs are keyed to the HIOS ID 14-digit identifier. This is too granular, and as we noted above, will lead to the generation of hundreds of thousands of files with repetitive information for in-network services and suppressed data for out-of-network (OON) and historical net prescription drug price fields.
  - HIOS ID 14 is too transient year-to-year. An issuer may not be able to report on a prior plan year's HIOS ID 14 if that plan no longer exists. Similarly, a new issuer or new plan under the issuer will have no historical data to report.
  - Therefore, we argue that the MRF would better be keyed at the HIOS 5-digit level. One level below, to identify the state, would be reasonable as well (HIOS ID 7).

[22] Public Law 116-260. See Section 204, which requires issuers report to the Secretaries of these departments the top 50 drugs in several categories and the effect of spending and rebates on premiums.
[23] For example, see https://www.healthaffairs.org/do/10.1377/hblog20200319.779429.
[24] See https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10725. The 30-day notice was posted in September 2020, with comments due October 2020. Revisions to the underlying regulations were proposed for the 2022 plan year in the Notice of Benefits and Payment Parameters proposed rule in December 2020 (85 Fed. Reg. 78572).

- It is at the HIOS 5-digit level that many of the contracted entities, including PBMs, operate with issuers, meaning that the data at more granular levels is simply repeated.
- Keying the MRF to the HIOS ID 5 or 7 also reduces confidentiality concerns and burdens on third-party vendors like PBMs, who would not need to parse out data at levels lower than contracted.
- HIOS ID 5 or 7 would also allow for the reporting of OON and historical net drug prices with minimal privacy-related data suppression.

- As defined in the regulation, only payments made to a provider are to be included in the OON file and historical net drug price calculations. CMS should clarify whether it intends for issuers to exclude reimbursement claims paid directly to members where there is no reimbursement to a provider. Most out-of-network pharmacy claims, for example, operate in this manner.
- Assuming CMS delays the MRF requirement by one year, CMS should confirm that the OON file and historical net prescription drug price field would not be published until 180 days after a plan is required to produce MRFs. For example, for a plan required to begin reporting MRFs on January 1, 2023, the need for reporting no earlier than July 2023 on OON file and historical net prescription drug price is to ensure that only sufficiently aggregated 90-day data is reported. Otherwise, between January and June 2023, these fields would be blank. Instead, the July 2023 file would include the period of January through March 2023.

B. Appendix 2 – In-network Rate File

- The rule states, "An in-network rate MRF that includes the required information under this paragraph (b)(1)(i) for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug machine readable file."
  - Can CMS confirm that "fee-for-service" here does not have the same meaning as it does for Medicare and Medicaid, and simply means not bundled or capitated?
  - For example, does CMS intend to exclude prescription drugs dispensed during the course of an emergency department, outpatient hospital, or inpatient hospital visit that are not paid separately but an episodic basis? "Bundling" and similar terms have specific meanings in various CMS programs and further clarification is needed.

C. Appendix 4 – Prescription Drug File

- Type of drug (branded, generic or biosimilar). Issuers (through their contracted PBMs) may not be able to disclose the type of drug for each dispensed NDC. The drug pricing compendia each have their own, slightly different definitions for what constitutes a generic drug, for example, based on the unique circumstances of the drug's marketing. Each compendia's determination is proprietary and likely not subject to public disclosure.
- With regard to in-network providers that are chains, CMS does not specify whether issuers should report historical net price and negotiated rate on a per-pharmacy basis compared to the parent level, e.g., in a retail chain pharmacy. We request CMS allow issuers the flexibility in approach to reporting drugs since prices may vary at these levels.

- We expect that CMS cannot feasibly collect in-network or historical net price data for patient prescription-specific compounded drugs and would appreciate confirmation.
- Are physician-dispensed prescription drugs, that are normally dispensed by retail, mail-order, or specialty pharmacies, intended to be captured in the prescription drug file or the in-network rate file? Many physicians (specifically specialty physicians) operate a limited dispensing pharmacy for the drugs they typically dispense.[25]
- Billing units and billing codes
  - The form indicates that negotiated prices and historical net prices are to be reported at the billing unit level as defined by NCPDP, contrary to the language of the final rule. This level of detail was not addressed or included in the final rule. CMS should instead grant issuers the flexibility to report as systems allow, consistent with the final rule.
  - Are pharmacy-dispensed diagnostics and devices intended to be captured in the prescription drug file? The service identifier is specifically listed as "National Drug Code." Some devices are identified with NDCs (and may be until September 2022 under Food and Drug Administration's (FDAs) Unique Device Identifier (UDI) guidance[26]) but others will be assigned UDIs. We caution CMS against any decision that will force issuers or their third-party administrators to change course midyear or for the subsequent year.
- Historical net price
  - As noted in Section I of this letter, we do not believe CMS has the authority to require the disclosure of historical net prices for prescription drugs. If it moves forward at significant risk in requiring this data element, the definition needs a substantial amount of work.
  - Allocation methodologies: If an issuer is paying retrospective quality bonuses not tied to drugs, do plans or issuers need to allocate those bonus payments to drugs and account for those as a "negative" price concessions in historical net price? We would note that these allocations may need to be reconciled with CMS's recent rule allowing for bundled sale incorporation into Medicaid Average Manufacturer Price and Best Price reporting.[27]
  - Time periods for price concession allocations: Identification of the time period prior to the current reporting period used for allocation reporting purposes, if the historical net price concessions are not known to the plan or issuer on the publication date of the file. The final rule merely requires that the allocation be made by using a "good faith, reasonable estimate" of the average price concessions based on a time period prior to the current reporting period and of equal duration. It does not require disclosure of the allocation method or time period serving as a basis for that good faith estimate. Requiring this data element is a significant expansion of the final rule.

[25] See for example https://www.accc-cancer.org/docs/projects/resources/pdf/dispensing-pharmacy-a-value-proposition-for-oncology-practices and https://communityoncology.org/wp-content/uploads/2019/09/COA-In-Office_Dispensing-PosStmnt-Final.pdf.
[26] See www.fda.gov/udi for more information on FDA's non-enforcement stance until September 24, 2022 for some Class I devices.
[27] See 85 Fed. Reg. 87000 (December 31, 2020).

- Reporting of fees: CMS would require that "transaction fee," "administrative fee," and "dispensing fee" be reported as separate fields.[28] All three fields should be excluded from the prescription drug file. The final rule does not require plans to disclose dispensing fees, but rather the amount a plan paid for a prescription drug, inclusive of dispensing fees.[29] HHS does not have authority to require distinct data elements in the ICR that were not included in the proposed or final rule.
- Further, based on the final rule, one would not expect any fee or other price concession types to be disclosed separately.[30] Rather, based on the definition of "historical net price" and the text from the preamble, rebates, discounts, chargebacks, fees and other price concessions are to be subtracted to calculate the final historical net price, not reported.

PCMA Recommendation: CMS should make the changes and clarifications noted in the section above following additional rulemaking as noted elsewhere in this letter, prior to re-issuing the ICR data collection forms for a subsequent round of public comment.

Conclusion

We thank CMS for the opportunity to provide comments on this important step toward the implementation of the Transparency in Coverage final rule. PBMs support the Administration's efforts to bring appropriate levels of transparency to prescription drug and other health care costs. If you need any additional information, please reach out to me at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs

CC: Kristin Bass, Chief External Affairs and Policy Officer, PCMA
Debjani Mukherjee, Senior Director, Regulatory Affairs, PCMA
Jeff Grant, Acting Director, CCIIO
Jeff Wu, Deputy Administrator, CMS

[28] In the case of "transaction fee" and "administrative fee," neither of these fee types is an amount paid by a plan for a prescription drug, nor do they impact the cost of the drug. A "transaction fee" is paid by the provider (i.e., pharmacy) to a PBM for the cost of maintaining advanced adjudication platforms. An "administrative fee" is paid by the plan to a PBM for certain services, such as claims adjudication.
[29] "Dispensing fee" should explicitly include vaccine administration fees and diagnostic test administration fees, as applicable, since PBMs are reimbursing pharmacies for these services.
[30] The preamble to the final rule states: "Historical net price means the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, **inclusive** of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug…" [emphasis added]. Later, CMS writes "Upon review of the comments, the Departments are of the view that public disclosure of the historical net price, **which takes into account** rebates, discounts, dispensing fees, and other price concessions, in addition to the negotiated rate, upon which cost sharing is based, provides the appropriate combination of pricing information to achieve the goals of transparency and ensure that individuals have access to meaningful prescription drug pricing information." [emphasis added]

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Submitted electronically via www.regulations.gov

March 1, 2021

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Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS–10715/OMB Control Number 0938-1372
Room C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Transparency in Coverage Information Collection Request (CMS-10715)

Dear Director Parham:

CVS Health appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) information collection request (ICR)[1] regarding implementation of the Transparency in Coverage final rule.[2]

Under the Final Rule—which was issued by the Departments of Treasury, Labor, and Health and Human Services (the Departments)— group health plans and health insurance issuers in the individual and group markets will be required to disclose consumer-specific estimated cost-sharing liability for covered items and services from a particular provider or providers through an internet-based self-service tool (SST) and in paper form upon request. This will be required for 500 covered items and services for plan years beginning in 2023 and for all covered items and services beginning in 2024. In addition, the Final Rule requires detailed health pricing information to be made public through three machine-readable files (MRFs) beginning in 2022. All three machine-readable files must be posted publicly and updated monthly.

CVS Health is a different kind of health care company. We are a diversified health services company with 300,000 employees united around a common purpose of helping people on their path to better health. In an increasingly connected and digital world, we are meeting people wherever they are, and changing health care to meet their needs. Built on a foundation of unmatched community presence, our diversified model engages 1 in 3 Americans each year. From our innovative new services at HealthHUB locations, to transformative programs that help manage chronic conditions, we are making health care more accessible, more affordable… and simply better.

At CVS Health, we believe that consumers need timely, accurate information about their out-of-pocket costs so they can make informed decisions as they shop for health care services and products. We are dedicated to providing meaningful, actionable information to our Caremark members and Aetna health plan enrollees through online consumer transparency tools. We are committed to working with CMS and with the Departments on out-of-pocket cost calculators, but

[1] *See* 85 Fed. Reg. 86567 (December 30, 2020), with relevant documents posted online on January 13, 2021 at https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10715.
[2] 85 Fed. Reg. 72158 (November 12, 2020).

the data elements requested in the MRF are not consumer-accessible and are not the right approach to support and achieve meaningful consumer transparency. Not only do the finalized and proposed MRF data elements not serve the goal of furthering a "shoppable experience" in healthcare for consumers who are focused on out-of-pocket costs, the MRF elements fall outside the scope of the authorizing statute and of the rule as proposed, they conflict with the new provisions in the Consolidated Appropriations Act of 2021, and they create an overly burdensome process for the industry that will not produce meaningful consumer tools. **We strongly recommend that you not move forward with this ICR, that you decline to implement the MRF portion of the final rule, and that you work with the Departments to rescind the MRF requirements entirely. If you cannot halt implementation of the MRF requirements, then a substantial implementation delay of one year or more is needed so operational, technical, policy, and competitive concerns can be addressed.**

1. The MRF portion of the final rule will not assist consumers in understanding their out-of-pocket costs

The Departments' final rule and the MRF data elements CMS has proposed in the ICR will not help consumers, who are focused on their out-of-pocket costs.

The final rule requires issuers to disclose in publicly-available MRFs negotiated rates and historical net prices for drugs at the National Drug Code (NDC) level for each applicable plan beginning in 2022. Historical net price is not a consumer-facing price or cost and it provides consumers with no information on what they will be required to pay for a drug at the pharmacy counter under their plan.

The release of this information will only make health care purchasing decisions more confusing and difficult for consumers. The information will not assist consumers with determining their out-of-pocket costs or making a value determination if quality information is not included as well. The information will, however, provide valuable information to manufacturers and others on what their competitors are being paid, paving the way for tacit collusion on pricing. The information allows those who have not negotiated as successfully with plans to raise their prices, setting a floor on the reimbursement for services and drugs that diminishes the negotiating leverage of plans and pharmacy benefit managers (PBMs), and will ultimately result in higher costs and premiums to the detriment of consumers and the market.

2. The proposed data elements are outside the scope of the authorizing statute

The prescription drug pricing data elements required in the MRF—most specifically, historical net price—are outside the scope of the authorizing statute. Prescription drug pricing data is not on the enumerated list of items that are to be reported to the Secretary found in Section 1311(e)(3) of the Affordable Care Act (ACA). Its inclusion in the final rule and ICR is inconsistent with the statute; it exceeded the Departments' authority to include it in the final rule and it exceeds CMS's authority to include it in the ICR.[3]

While the Departments attempt in the preamble to the Final Rule to justify its inclusion by reliance on a broad catch-all phrase ("Other information as determined appropriate by the Secretary"), this is not supportable given the very specific items previously listed in the statute. While Congress very clearly gave the Secretary the ability to require the reporting of "other

[3] *City of Arlington v FCC* 569 U.S. 290, 297 (2013) (an agency must stay "within the bounds of its statutory authority"). See also *Ciox Health LLC. V. Azar et. al*, No. 18–cv–0040–APM (D.D.C. January 23, 2020).

information" similar to that specifically enumerated in the statute, it did not grant the Secretary the ability to require reporting of information outside-the-scope or dissimilar to those items already listed.[4] The catch-all item does not grant the Secretary the ability to require reporting of information outside-the-scope or dissimilar to those items already listed.

3. The finalized "historical net price" element was not included in the proposed rule

Further, the inclusion of historical net price was not included in the proposed rule. As such, there was no public opportunity to comment on it or raise concerns about its inclusion. Given that this is a central concept and data element required by the Final Rule and listed in the forms included in the ICR, the failure to mention it in the proposed rule and allow comment is a fatal deficiency in the rulemaking process. CMS may not now move to implement this, and should CMS wish to proceed with requiring this data element despite the statutory concerns, the agency must issue a new notice of proposed rulemaking to allow full public comment and address the operational, competitive and policy concerns raised in any final rulemaking.

4. The requirements are at odds with the recently-passed CAA

Furthermore, the requirements conflict with the recent reporting requirements regarding drug costs included in the Consolidated Appropriations Act of 2021 (CAA),[5] enacted December 27, 2020. These new reporting requirements for group health plans and health insurance issuers are intended to achieve similar objectives as those articulated by the Departments in the Final Rule and by CMS in the ICR supporting statement, but do so in a much more focused and thoughtful manner, and while preserving confidentiality so as to avoid the negative competitive consequences that will flow from the MRF public reporting requirements. The inclusion of very different prescription drug reporting requirements and confidentiality protections in the CAA, barely a month following the issuance of the Final Rule, signals Congress is not aligned with this approach to MRFs and underscores the lack of authority for the direction of the Final Rule.

5. The MRF requirement is overly burdensome

The MRF requirement, as specified in the Final Rule and further elaborated upon in the ICR documents, will impose significant operational burdens on affected plans and their service providers at a time when resources are already stretched thin by the COVID-19 public health emergency. It requires detailed information that must be pulled from various sources and updated on a monthly basis. This will be an extremely resource-intensive endeavor, far exceeding the estimates included in the ICR by CMS. This tremendous burden is exacerbated by unclear and conflicting definitions and descriptions of terms between the Final Rule and ICR documents, and even within the ICR documents themselves. As such these MRFs cannot be implemented by January 1, 2022, and if not halted entirely the requirement must be delayed by at least one year.

As a whole, the machine-readable file (MRF) data elements for the in-network rate and historical out-of-network allowed amount are complex and, as proposed, would require the production of an exponential number of files due to the duplication of data elements required for each file –

[4] *Gooch v. United States*, 297 U.S. 124, 128 (1936). *Accord Hall St. Assocs., L.L.C. v. Mattel, Inc.*, 552 U.S. 576, 586 (2008) ("Under that rule [of ejusdem generis], when a statute sets out a series of specific items ending with a general term, that general term is confined to covering subjects comparable to the specifics it follows.").
[5] Public Law 116-260. *See* Section 204, which requires issuers report to the Secretaries of these Departments the top 50 drugs in several categories and the effect of spending and rebates on premiums.

we estimate tens of billions of records. For example, when reporting at the Employer Identification Number (EIN) level, and EIN can be utilized for multiple plan products in multiple markets. Listing these files according to the requirements will produce several files with the same EIN containing different contracted rates across items and services. Subsequently releasing such a large volume of complex information will not be reflective of variations in actual costs and will ultimately lead to misinterpretation and misrepresentation by users.

Additionally, there are foundational problems with the MRF data elements in both the final rule and in the ICR. First, many of the data elements utilize an "either/or" functionality which will lead to non-standardized data, which in turn will be ultimately unusable in making a true comparison between providers and services. Second, many of the data elements listed in the Appendices were added or revised from the initial Transparency in Coverage file architecture within the proposed rule to the finalized rule. Many of these changes add an additional layer of information exposure and increase the complexity of file reporting exponentially. For instance, within the allowed amount file, a plan may not be able to report on a prior year Health Insurance Oversight System (HIOS) identifier and/or EIN if the plan no longer exists; a code set doesn't exist to map to provider type, specialty or multiple specialty; providers can have multiple National Provider Identifiers (NPI) registered with CMS which will be extremely difficult to map within each file; additionally, a provider can operate at multiple geographical locations using the same place of service code under the same NPI, which adds complexity in differentiating rates.

* * * *

CVS Health is committed to providing consumers with actionable information regarding their drug and other health costs to enable them to make informed decisions on their health care options, and we believe that the SST and our own cost-calculator tools are the best path towards achieving this goal. In contrast, the MRF requirement takes a step in the wrong direction, raises serious policy and competitive issues, and is being imposed in a manner and timeframe that has not allowed the appropriate public input and consideration and fails to comply with the Administrative Procedure Act. **We therefore strongly recommend that CMS halt implementation of the MRF requirement and work with the Departments to rescind this requirement entirely. If CMS cannot halt implementation of the MRF requirement, it must delay implementation by a year or more.**

A more detailed discussion of our recommendations is provided in the attached appendix.

We thank CMS for the opportunity to provide comments at this step in the implementation of the Transparency in Coverage final rule, and we are committed to working with CMS as it formulates rules and policies that advance meaningful, actionable transparency for consumers. We would be happy to respond to any follow-up questions you may have.

Sincerely,

Melissa Schulman
Senior Vice President
Government & Public Affairs

1275 Pennsylvania Ave NW, Suite 700
Washington, DC 20004

APPENDIX COMMENTS

Appendix 2: In-network Rate Machine-Readable File Data Elements

Negotiated Rate for each covered item or service; Underlying fee schedule rate for each covered item or service.

- Contracts can have specific rates for each provider service location. Therefore, if a provider operates in multiple geographic locations, there isn't a way to differentiate rates by service location. If such a data element was added, this would increase the number of files produced.

Payment Arrangement Indicator

- Incorporating this data element would produce meaningless information for the consumer and introduce confusion since no two value-based contracts are identical between health plans, nor are they meant to be given the focus on local populations and provider quality metrics, thus there isn't a way to utilize this data element as a piece of meaningful consumer information. By putting this information out in a public file will also lead to potential gaming by file users, creating unintended market consequences based on inaccurate comparison data.

Additionally, capitation for a service depends on provider selection, plan design and the age of the member. To accurately account for capitation, this information would need to be mapped to a current procedural terminology (CPT) code to the capitated arrangement is aligned to.

Appendix 3: Allowed Amount Machine-Readable File Data Elements

The "unique out-of-network allowed amount" will also introduce confusion and potential inaccuracies for both consumers and third parties who want to utilize the data as a meaningful indicator of service or our-of-pocket cost. Reporting this information will likely impact plan networks by incenting in-network providers to move out-of-network, increasing costs for consumers and the health care system, additionally putting plans at risk of noncompliance with network adequacy standards and available in-network providers for health plan members.

This data element also runs against the recently passed Consolidated Appropriations Act, No Surprises Act provisions related to transparency and the prohibition on surprise billing. Thus, we recommend rescinding the machine-readable file requirements to review the transparency environment, how the legislation and regulations interact, and determine if the effort is meeting the intended outcome of providing consumers with meaningful and actionable information.

Appendix 4: Prescription Drug File

The Department of Health and Human Services does not have authority to require new, distinct data elements in the ICR that were not included in the final rule. Fields that were never contemplated by or included in the rule and are therefore impermissible in the ICR are:

- The fields "transaction fee," "administrative fee," and "dispensing fee." Not only are these fields not discussed or included in the final rule, but "administrative fee" and "transaction fee," as described, have nothing to do with historical net price, nor is any rationale provided for their inclusion. While "dispensing fee" would be a component of "negotiated rate," in the preamble to the final rule, the Departments specifically reference

comments recommending that it not require reporting at this level because of the highly competitive nature of this information.[6] Accordingly, the Departments chose not to require reporting at this level, stating that reporting the negotiated rate and historical net price takes these types of fees "into account" and provides "the appropriate combination of pricing information to achieve the goals of transparency."[7] Therefore, requiring reporting at this level is not only contrary to the regulatory language, but also to the Departments' own statements as to the appropriate level of reporting in the preamble to the final rule, and at odds with its own conclusion that negotiated rate and historical net price provide "sufficient transparency."[8]

- The field "historical net price allocation reporting period," which identifies the time period prior to the current reporting period used for allocation reporting purposes if the historical net price concessions are not known to the plan or issuer on the publication date of the file. The final rule merely requires that the allocation be made by using a "good faith, reasonable estimate" of the average price concessions based on a time period prior to the current reporting period and of equal duration. It does not require disclosure of the allocation method or time period serving as a basis for that good faith estimate. Requiring this data element is a significant expansion of the final rule.
- The field for the type of drug (branded, generic, or biosimilar). This data element is not required by the final rule, nor is it necessary given that reporting is already at the NDC level. CMS cannot impermissibly expand the scope of the final rule by adding a data element that was not proposed, mentioned, or addressed in any way.
- Requiring reporting of negotiated price and historical net price at the "billing unit level as defined by NCPDP". Again, this data was not addressed or included in the final rule. In fact, the final rule explicitly acknowledges that "there is wide variability in how negotiated rates are assigned for prescription drugs" and "[t]o allow for flexibility, . . . the final rules do not assign a benchmark or necessary inputs to the definition of negotiated rates."[9]

We again stress that since the collection of historical net price was not proposed, and adding it through a subregulatory process violates the notice and comment rulemaking requirements imposed on the agency under the Administrative Procedure Act (APA).

Finally, the final rule requires the reporting of HIOS or EIN identifiers. This is inappropriate for multiple reasons: it was not included in the proposed rule and thus violates APA rulemaking requirements, it is not information that PBMs collect or maintain, and requiring it would be overly burdensome. The failure to allow proper notice and comment is not only unlawful but practically speaking deprived the public of the opportunity to explain that HIOS or EIN data are not currently collected, and establishing a new requirement to capture, store, and maintain this information on an ongoing basis would be costly and burdensome without providing meaningful or helpful information to consumers.

[6] 85 Fed. Reg. at 72197.
[7] 85 Fed. Reg, at 72238.
[8] 85 Fed. Reg. at 72337.
[9] 85 Fed. Reg. at 72235.

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March 1, 2021

VIA ELECTRONIC SUBMISSION TO www.regulations.gov

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier CMS-10715 /OMB Control Number 0938-1372
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Agency Information Collection Activities: Proposed Collection; Comment Request [Title of Information Collection: Transparency in Coverage Final Rule]; CMS-10715 (OMB control number 0938-1372)

To Whom It May Concern:

Cigna welcomes the opportunity to respond to the Paperwork Reduction Act of 1995 notice regarding "Agency Information Collection: Proposed Collection; Comment Request" associated with CMS-10715—Transparency in Coverage (OMB control number 0938-1372) issued by Centers for Medicare & Medicaid Services (CMS) (the "Transparency in Coverage PRA Notice").[1] Cigna appreciates CMS's efforts to allow the public to comment on burden estimates and any other aspect of the information collection associated with the Transparency in Coverage final rule, 85 Fed. Reg. 72158 (Nov. 12, 2020). Cigna supports the goal of providing consumers with information on price and quality that will enable them to evaluate health care options and make decisions that are right for them. However, Cigna has concerns about the information collection associated with the Transparency in Coverage final rule.

Cigna Corporation, together with its subsidiaries (either individually or collectively referred to as "Cigna"), is a global health service organization dedicated to helping people improve their health, well-being, and peace of mind. Our subsidiaries are major providers of medical, pharmacy, dental, disability, life and accident insurance, and related products and services, with over 175 million customer relationships in the more than 30 countries and jurisdictions in which we operate. Worldwide, we offer peace of mind and a sense of security to our customers seeking protection for themselves and their families at critical points in their lives.

[1] 85 Fed. Reg. 86567 (Dec. 30, 2020).

Within the U.S., Cigna provides medical coverage to approximately 14 million Americans in the commercial segment. We also provide coverage in the individual Affordable Care Act insurance segment in several states, both on- and off-Exchange, to about 235,000 people. Additionally, we serve more than 4.5 million people through our Medicare Advantage, Medicare Prescription Drug Program and Medicare Supplemental products.

With that context as background, Cigna offers the following comments on the Transparency in Coverage PRA Notice.

* * *

Cigna supports the goal of providing transparency to consumers through the sharing of meaningful, actionable information that encourages informed health care choices and competition. Providing our customers with convenient access to personalized information about the cost and quality of care has long been one of our principal priorities. Consistent with Cigna's aim of making health care affordable, predictable and simple for our customers, we designed and have been offering industry-leading tools to help our customers make informed health care decisions, including the ability to view real-time cost-sharing information for prescription drugs and more than 1,000 medical procedures. We believe CMS is right to focus on guaranteeing all Americans have access to personalized information about the cost and quality of medical services before seeking care. However, we note that, as stated in Cigna's comments submitted in response to the Transparency in Coverage proposed rule, Cigna has key concerns with the approach taken by CMS, the Internal Revenue Service and the Employee Benefits Security Administration (collectively the "Departments"). [2]

Furthermore, Cigna has reviewed the Transparency in Coverage final rule's associated information collection requirements and raises the following four areas of concern: (1) concerns regarding the unintended consumer confusion or misinformation; (2) the need to minimize information collection burden associated with the requirement to share individual cost-sharing liability estimates (the "cost calculator" tool) ; (3) the data elements enumerated in the Transparency in Coverage PRA Notice appendices that exceed the scope of the final rule; and (4) concerns with the use of GitHub as a platform to share CMS's technical implementation guidance.

I. Potential for Consumer Confusion or Misinformation, an Unintended and Counterproductive Outcomes, Associated with Machine-Readable Files

Cigna is concerned significant portions of information collection associated with the Transparency in Coverage final rule are neither necessary nor useful for CMS's achievement of its stated goals. Indeed, we are very concerned that the rule's requirements are in fact counterproductive to the goals of the final rule, which were articulated as follows: (1) to engage, support and enhance the ability of consumers to choose the health care that is best for them; (2) to reduce potential surprises in relation to consumers' out-of-pocket costs; and (3) to create a competitive dynamic that may narrow price dispersion and put downward pressure on prices, which may in turn potentially lower overall health care costs. In particular, the final

[2] Cigna Comments on Transparency in Coverage Proposed Rule (Jan. 29, 2020), https://www.regulations.gov/comment/CMS-2019-0163-19728 (downloaded Feb. 22, 2021).

rule's requirements involving public disclosure of negotiated rates and historical pricing data in machine-readable files will not be useful for CMS in its efforts to meet these goals.

As a means of enhancing and supporting consumer decision-making and reducing potential surprises in out-of-pocket costs, machine-readable file data in its raw form will not be useful to consumers because such massive amounts of data will not be personalized, meaningful, and actionable. As a result, the machine-readable file data will not be useful to inform health care choices, nor will it be helpful to reduce potential surprises in out-of-pocket costs. Such data is simply not consumer-friendly. Third party application developers may be able to use such data, but they will not have access to enrollee benefit information and accumulators. Therefore, the information third parties can provide to consumers will be incomplete and even potentially misleading because the machine-readable file data used will not allow for sufficient specificity to the consumer's individual situation.

Moreover, the machine-readable file data likely will not create competition that lowers prices and overall health care costs. Rather, potential anti-competitive effects may result from the disclosure of the data that could hinder negotiations and drive up prices. Independent analyses by the Federal Trade Commission and the Minnesota Department of Human Services have raised concerns that too much transparency, particularly relating to pricing and rates between providers and payers, potentially reduces competition and leads to higher prices.[3] Particularly in the wake of the continuing trend of health care provider consolidation, providers have increased pricing power and, given access to information on prices paid to their competitors, can wield it to extract higher rates for services. In this way, price transparency may facilitate tacit collusion between providers. Public disclosure of negotiated payment rates, including those delineated by billing codes for individual providers and plans, would remove leverage during negotiations, hinder competition, and increase prices.

It is also important to note the experience to date with CMS's recently implemented requirement that hospitals make standard charges available for all of the items and services they offer. Although the hospitals were required to be compliant by January 1, 2021, a recent Guidehouse analysis found that 30% of hospitals have not complied with any aspect of the hospital transparency requirements. Analysis of the hospital data shared to date has found that such data are inconsistently derived and therefore generally not meaningful.

Because CMS's issuer machine-readable files requirements will not meet CMS's program goals of supporting consumer choice and fostering lower pricing and health care costs, the information collection is neither necessary nor useful to CMS's stated goals in its regulation.

II. Minimizing Consumer Premium Impacts Driven by Unnecessary Administrative Costs, and Instead Building Upon Existing and Effective Consumer Cost Calculator Tools

Our concerns with the rule's requirements in isolation were exacerbated by overlapping requirements contained in the Transparency in Coverage final rule and the Consolidated Appropriations Act, 2021 ("CAA"). We urge CMS to rationalize overlapping requirements to: (1) maximize existing, successful

[3] See Koslov, T. and Jex, E., *Price transparency or TMI?,* Federal Trade Commission Blog (Jul 2, 2015) https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi (downloaded Feb. 17, 2021); Minnesota Department of Human Services, *Health Care Contracting and the Minnesota Government Data Practices Act* (February 2015), https://mn.gov/dhs/assets/Health_Plan_Data_Report_tcm1053-166426.pdf (downloaded Feb. 17, 2021).

consumer transparency tools in the market and allow continued innovation; and (2) avoid the imposition of avoidable and unnecessary administrative costs on a system already struggling to achieve affordability for all.

The Transparency in Coverage final rule requires plans and issuers to disclose cost-sharing information upon request to an enrollee, including an estimate of the individual's cost-sharing liability for covered items and services furnished by a particular provider. Plans and issuers must make this information available on an internet website (using what may commonly be termed a "cost calculator" tool) and, if requested, in paper form. The Departments will require implementation of this regulatory requirement by January 1, 2023 for 500 items and services, and by January 1, 2024 for all items and services.

In the recently enacted CAA, Section 114 of the No Surprises Act (Division BB of the CAA) requires health plans or issuers to maintain a "price comparison tool" that "shall offer price comparison guidance by telephone and make available on the Internet website of the plan or issuer a price comparison tool." The implementation date of Section 114 is January 1, 2022.

These two overlapping requirements give rise to concerns about administrative costs and affordability. Cigna recommends the Departments consolidate the Transparency in Coverage "cost calculator" requirement and the CAA price comparison tool requirement as a means of streamlining and minimizing burden associated with these similar provisions. It is neither necessary, nor useful to consumers, to have two separate and competing tools. Moreover, Cigna recommends the Departments align their regulatory efforts with Section 114's requirement to share information by phone or internet, and consider rescinding the regulatory requirement to require information by paper upon request.

The applicability dates of these two requirements vary significantly. Cigna recommends the applicability dates be aligned to allow full and thoughtful consideration of what Congress intended and the scope of what and how such price/cost comparison tools should be structured to benefit consumers. Cigna recommends that implementation of both the CAA price comparison tool and the Transparency in Coverage "cost calculator" tool and associated cost-sharing requirements occur no sooner than January 1, 2023 for CMS's specified 500 items and services, and no sooner than January 1, 2024 for any remaining items and services.

Moreover, Cigna has long developed and offered our customers personalized cost calculator tools that have been highly valued and proven effective in empowering our customers with the cost and quality information they need to make value-based choices for themselves and their families. We would be happy to demonstrate those tools to CMS and the Departments so that they might consider a regulatory approach that builds upon private sector innovations, rather than cementing those tools in a regulatory construct with less utility than what is already supporting patients.

III. Data Element Concerns

Cigna has concerns regarding specific prescription drug machine-readable file data elements in Appendix 4 of the Transparency in Coverage PRA Notice supporting materials. CMS should not require separate reporting of data elements for "transaction fee," "administrative fee," and "dispensing fee" as listed in Appendix 4.

CMS has defined historical net price in regulation to mean:

> . . . the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, *inclusive* of any reasonably allocated rebates, discounts, chargebacks, fees and any additional price concessions received by the plan or issuer with respect to the prescription drug.[4] [emphasis added]

Furthermore, the Departments were clear in the final rule preamble that:

> [P]ublic disclosure of the historical net price, which takes into account rebates, discounts, dispensing fees, . . . in addition to the negotiated rate upon which cost sharing is based, provides the appropriate combination of pricing information to achieve the goals of transparency and ensure that individuals have access to meaningful prescription drug pricing information.[5]

The term "fees" in the regulatory definition of "historical net price" includes any type of fee, including transaction, administrative, and dispensing fees. Therefore, such fees will be included in the historical net price disclosure and should not be subject to separate reporting.

To require separate reporting of transaction, administrative, and dispensing fees is clearly beyond the scope of what the final rule requires. Cigna strongly recommends removal of dispensing fees, administrative fees, and transaction fees from the required data elements associated with the prescription drug machine-readable files.

IV. GitHub Concerns

Finally, Cigna is concerned regarding CMS's use of GitHub as the means of issuing technical implementation guidance. CMS states in footnotes to the Transparency in Coverage PRA Notice appendices 2, 3 and 4, the public is to find "more technical implementation guidance for this machine-readable file" at a specific landing page on the Github.com website. The open-source nature of GitHub as a platform for sharing governmental guidance will create unnecessary confusion for plans and issuers seeking to comply with the Transparency in Coverage final rule's requirements. We are concerned the use of GitHub will result in uncertainty as to exactly what information represents original governmental guidance, as opposed to posting of information by private parties. In the absence of clarity as to source, any posting of information is unreliable as guidance to the public.

Moreover, where governance is required and there is the potential for a high frequency of changes or modifications offered, GitHub is not a suitable platform. In this case, there may be a large audience and a high frequency of changes offered on the technical implementation of the Transparency in Coverage final rule's requirements and implementation. Because GitHub is an open platform with postings from many private parties, modifications to original postings can be confused with original postings by the government. We understand the Departments seek to respond to technical and compliance questions or needs in a collaborative fashion via GitHub, but we are concerned the platform will heighten confusion as to what is truly guidance from the government.

Cigna recommends all original postings of technical implementation guidance from the Departments to GitHub be separately posted on the CMS website and the public be provided adequate notice of such

[4] 85 Fed. Reg. at 72305 (promulgating the regulatory definition of "historical net price" at 45 CFR 147.210(a)(2)(xi)).
[5] 85 Fed. Reg. at 72238.

guidance. If interactions on GitHub give rise to CMS or Departmental changes to technical implementation guidance associated with the Transparency in Coverage final rule, such changes should also be posted separately on the CMS website with adequate public notice. Such postings will enable clear understanding of the technical implementation guidance actually offered by CMS and the Departments. We note that anything regulatory in nature should be subject to formal notice-and-comment rulemaking.

Conclusion

Cigna appreciates the opportunity to comment on this Transparency in Coverage PRA Notice. Cigna shares CMS's goal of empowering consumers to make the best decisions regarding their health care by providing them with information on price and quality. However, we believe the rule's requirements are counterproductive to the stated goals. We urge CMS and the Departments to consider a modified approach that minimizes unnecessary administrative burden on the health care system, builds upon and allows for innovation and competition to achieve affordability, and most importantly, provides American patients and consumers with a reliable source of information that is relevant to them. Cigna stands ready to work with CMS to increase price and quality transparency that is meaningful, actionable, and consumer-friendly and that furthers our shared goal to improve affordability and value in the health care system.

Thank you for your consideration of these comments. Cigna would welcome the opportunity to discuss these issues with you in more detail at your convenience.

Respectfully,

Kristin Julason Damato
Vice President

UNITEDHEALTH GROUP

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March 1, 2021

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
7500 Security Boulevard
Baltimore, MD 21244–1850.

Submitted Electronically: www.regulations.gov

Re: Information Collection Request – Transparency in Coverage (CMS-10715)

Dear Sir/Madam:

UnitedHealth Group (UHG) is pleased to respond to the Information Collection Requests (ICRs) published by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on December 30, 2020 (85 FR 86567). The ICRs support requirements outlined in the Transparency in Coverage Final Rule issued by the Departments of Health and Human Services, Labor, and the Treasury (the "Tri-Agencies") on November 12, 2020 (85 FR 72158).

UnitedHealth Group is a mission-driven organization dedicated to helping people live healthier lives and helping our health care system work better for everyone through two distinct business platforms – UnitedHealthcare (UHC), our health benefits business, and Optum, our health services business. Our workforce of 325,000 people serves the health care needs of 142 million people worldwide, funding and arranging health care on behalf of individuals, employers, and the government. We not only serve as one of the nation's most progressive health care delivery organizations, we also serve people within many of the country's most respected employers, in Medicare serving nearly one in five seniors nationwide, and in Medicaid supporting underserved communities in 31 states and the District of Columbia.

UHG supports polices enabling patients and their caregivers to exchange information to improve health outcomes and better inform care decisions. We are actively engaged in initiatives to to ensure our members and health care providers receive clear and complete information about the cost and quality of care including:

- *MyUHC.com* and the *UHC App* engaging consumers with information on claims, provider costs, health plan details, digital ID cards, and information on deductibles and copayments.

- *Rally Connect*® creating a comprehensive picture of what consumers should expect during their treatment and allowing comparisons of treatment options and quality information across sites of service.

- *Pre-Check MyScript*® allowing providers to view and share real-time cost, coverage, and safety information with patients.

- *MyScript Finder*® giving consumers information on out-of-pocket costs for prescription drugs based on the location of the pharmacy, benefit plan design, and cost-sharing.

UHG comments below offer specific recommendations on ways to further streamline the four ICRs. In addition, we address two over-all issues with respect to the Health Plan Transparency Final Rule.

General Comments Regarding Transparency in Coverage

The Health Plan Transparency Final Rule imposes two obligations on health insurance issuers and group health plans. First, beginning with plan and policy years on or after January 1, 2022, insurers and plans must make three machine-readable files available to the public with detailed information on the following: (a) in-network provider rates; (b) out-of-network allowed amounts and billed charges; and (c) negotiated rates and historical net prices for covered prescription drugs In addition, beginning with plan and policy years on or after January 1, 2023, insurers and plans must provide members with a cost-estimator tool with in-network and out-of-network cost-sharing estimates and other information related to covered items and services.

UHG and other insurers and group plan administrators are expending significant resources across administrative, operational, and information technology systems to implement the transparency rule provisions. These efforts are in addition to insurer and plan activities to comply with other regulatory and statutory mandates including the Health Plan Interoperability Rules from CMS (85 FR 25510) and the Office of the National Coordinator for Health Information Technology (85 FR 25642) and the extensive new requirements imposed by the Consolidated Appropriations Act (CAA) (PL 116-260) that must be implemented beginning in 2022. Work on these programs is further complicated by the need to meet the challenges imposed by the COVID-19 pandemic including programs devoted to testing, treatment, and vaccinations.

The Tri-Agencies should consider extending implementation of the machine-readable file provisions of the Health Plan Transparency Rule for an additional year, to be effective for plan and policy years beginning on or after January 1, 2023. The machine-readable file provisions require insurers and plans to produce a significant amount of detailed information and update those files monthly. It is critical for insurers and plans to have sufficient resources to adequately meet their implementation obligations for the transparency rule as well as other on-going compliance activities. A one-year extension will give insurers and plans sufficient time to compile and organize the large volume of health data spread across multiple systems and platforms that will be needed to populate the files and make them available.

UHG recommends CMS work with the Tri-Agencies to adopt a one-year extension of the Health Plan Transparency Final Rule requirements to make machine-readable files publicly available. As a result, the machine-readable files would be available for plan and policy years beginning on or after January 1, 2023.

The CAA establishes requirements for health insurers and group health plans to assist enrollees with cost comparisons of covered health care items and services:

> A group health plan or a health insurance issuer offering group or individual health insurance coverage shall offer price comparison guidance by telephone and make available on the Internet website of the plan or issuer a price comparison tool that (to the extent practicable) allows an individual enrolled under such plan or coverage, with respect to such plan year, such geographic
> region, and participating providers with respect to such plan or coverage, to compare the amount of cost-sharing that the individual would be responsible for paying under such plan or coverage with respect to the furnishing of a specific item or service by any such provider.

(CAA, Division BB, Section 114). This provision is effective for plan and policy years beginning on or after January 1, 2022.

UHG suggests the Tri-Agencies coordinate compliance with the CAA price comparison provisions and the implementation date of the Health Plan Transparency Rule requirements for making a cost-estimator tool available. The Tri-Agencies should issue guidance to clarify that health insurers and group health plans that are making good faith efforts to implement the Health Plan Transparency Final

Rule are likewise in compliance with the price comparison provisions of the CAA in Division BB, Section 114.

Insurer and plan members will have sufficient tools available to understand price comparisons in the interim prior to the January 1, 2023 implementation date of the cost-estimator tool provisions of the transparency rule. As discussed above, UHG – like many other insurers and plan administrators - currently makes cost-estimate information available to members on the internet and through customer service centers.

There are also other required transparency disclosures and tools required under the CAA which will impact efforts to make cost-estimate information available through a self-service internet tool. For example, the CAA requires insurers and plans to provide members with an advance Explanation of Benefits statement with cost-sharing estimates when medical services are scheduled in advance (CAA, Division BB, Section 111). Other CAA provisions will protect consumers from surprise medical bills and place limits on balance billing by out-of-network providers, which will further inform consumers of potential medical charges and protect against unexpected out-of-pocket costs (*see:* CAA, Division BB, Title I, Sections 102 – 105).

UHG recommends CMS work with the Tri-Agencies to issue guidance clarifying that health insurers and group health plans that are making good faith efforts to implement the Health Plan Transparency Rule requirements to make a cost-estimator tool available to members beginning with plan and policy years on or after January 1, 2023 are in compliance with the CAA requirements in Division BB, Section 114 to provide cost-estimates to members.

Transparency in Coverage Model Notice (Appendix 1)

Appendix 1 of the ICRs is a model form for insurers and plans to use when making cost estimate disclosures to members. The notice includes definitions of key terms and required disclaimers such as the fact that the disclosure is an estimate of costs and that actual charges may differ. The model notice language can be used when members request a written disclosure of estimated costs and as part of the internet self-service tool.

The model disclosure form is complicated with a readability level that appears to be too high for the average reader. The format is not user friendly and the form does not include a section to set out the required information about estimated charges and costs that must be disclosed to a member. We also note that the disclaimers and other information on the form do not reflect the disclosures that will be required by the CAA. For example, the disclaimers related to the potential for balance billing by out-of-network providers will need to be extensively revised to reflect the CAA limits on surprise medical bills.

UHG suggests CMS revise the form to make it more readable and understandable to the average reader and that the form be reviewed by consumer focus groups to ensure it effectively communicates the information. The changes to the form should include information disclosures required by the CAA as well as a section for information about costs and charges required to be disclosed by the Health Plan Transparency Rule.

UHG recommends CMS revise the model disclosure form to make it more understandable and to reflect the information disclosure requirements in the CAA. In addition, the form should include a section for the disclosure of the estimated charges and cost-sharing information.

The disclaimer that coverage of an item or service may be subject to a prerequisite includes a discussion of prior authorization indicating the insurer or plan "must decide whether this item or service is medically necessary before it will cover this item or service." (Appendix 1 at p. 4). It is clear then that prior authorization is a prerequisite in this context. However, the instructions and model notice do not provide clear or complete guidance on what other terms and conditions should be included as prerequisite. For example, the model disclaimer discussion of concurrent review does not reference medical necessity. The definition of Prerequisites should be revised to incorporate the concept of medical necessity with respect to concurrent reviews of items and services.

UHG recommends revising the definition of prerequisites to clarify that medical necessity may be included in a concurrent review determination by the insurer or plan.

Machine Readable Files (Appendices 2, 3, and 4)

All three machine-readable file formats require data for the "Name of Reporting Entity" and "Type of Reporting Entity." The Name of Reporting Entity is unnecessary because in many cases the same information will be disclosed under the "Plan or Coverage Name" designation.

The "Type of Reporting Entity" is defined as follows:

> The type of entity that is publishing the machine-readable file (a group health plan, health insurance issuer, or a third-party with which the plan or issuer has contracted to provide the required information, such as a third-party administrator, a health care claims clearinghouse, or a health insurance issuer that has contracted with a group health plan sponsor).

(Appendices 2, 3, and 4 at p. 1).

This information disclosure is not required by the Health Plan Transparency Rule and is unnecessary for the underlying purpose of making the machine-readable files available to the public – that is, to facilitate understanding of the negotiated rates and historical cost data for health insurers and group health plans for covered items and services. There is also the potential for confusion where the reporting entity is different from the insurer or plan for which the data is displayed (e.g., XYZ Clearinghouse is reporting for ABC Employer). It may be unclear to some consumers accessing the machine-readable files whether the information in the machine-readable file is for coverage offered by the reporting entity (e.g., the plan administrator or clearinghouse) or the reported plan or coverage.

UHG recommends revising the three machine-readable file formats to remove references to the "Name of Reporting Entity" and "Type of Reporting Entity" to avoid the potential confusion and because the inclusion of name and type of reporting entity is not required by and does not serve to advance the purposes of the Health Plan Transparency Rule.

There are certain data elements required on one or more of the machine-readable file formats that may be not be available. For example, some health care providers such as certain behavioral health providers, do not have a National Provider Identifier (NPI). The Provider Group Identifier may not be appropriate if the provider is not part of a practice group. The Contract Term for Negotiated Rate is not available if the insurer or plan and provider do not have a specified expiration or termination date for their contract and the agreement does not include a schedule or pre-determination date for any changes to the payment rates. The model forms in these cases should indicate that "Not Available," "Not Applicable," "NA" or another appropriate indicator may be substituted where the data is not available at the time the machine readable file is updated.

UHG recommends the machine readable file formats clarify when "Not Available," "Not Applicable," "NA" or other designation may be used to indicate that information is not available for the data element.

Additional clarification is needed to describe some of the pricing and cost data requirements. For example, in some cases the Negotiated Rate for Each Covered Service may be the same as the Underlying Fee Schedule Rate. In this situation, should the same amount be included in both fields? Or should it be reflected in the Negotiated Rate field and the Underlying Fee Schedule Rate be indicated as "not applicable" or vice-versa – include the rate in the Underlying Fee Schedule Rate and indicate that the Negotiated Rate field is "NA" (or other similar designation)?

The Payment Arrangement Indicator on the In-Network Rate Machine Readable File (Appendix 2) is defined as "(a)n indication as to whether a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies" It would be helpful to provide standard designations

or codes that can be used across insurers and plans to indicate the type of arrangement for consistency and clarity of understanding for stakeholders.

UHG recommends CMS revise information on the machine-readable files to: (a) clarify situations where the negotiated rates and underlaying fee schedule rates are the same and (b) provide standard designations or codes for the payment arrangement indicator.

The Allowed Amount Machine-Readable File (Appendix 3) includes data requirements for the Unique Out-of-Network Allowed Amount and the Billed Charge. Disclosure of this information is required by the Health Plan Transparency Rule, As discussed in our comments in response to the proposed Health Plan Transparency Rule, we continue to be concerned about the potential member confusion and anti-competitive impacts of required disclosure of allowed amounts. The end result may be higher overall health care costs and less innovation.

There are three issues with respect to this data in the machine-readable file that should be clarified. First, the file format should indicate whether the time period for capturing the Unique Out-of-Network Allowed Amount is the same as that for the Billed Charge (i.e., the 90-day time period that begins 180 days prior to the publication date of the file). We believe the Health Plan Transparency Rule anticipates the same timeframe for both data elements, but the disclosure timeframe for the Billed Charge should be specified in the file format.

In addition, CMS should clarify the first reporting date for the Unique Out-Of-Network Allowed Amount and Billed Charge. As noted, the file should include the "(u)nique out-of-network allowed amounts and billed charges with respect to covered items or services furnished by out-of-network providers during the 90-day time period that begins 180 days prior to the publication date of the machine-readable file . . . ." (45 CFR §147.212(b)(1)(ii)(C)). If the Tri-Agencies do not extend the implementation date of the machine-readable files, CMS should confirm that this data would not be published in 2022 until 180 days have passed, no sooner than July 2022.

Finally, we request that CMS make clear that the allowed amounts not include any claims for reimbursement paid directly to a member, and not to the provider. There are certain coverage designs – in particular involving out-of-network items and services – where the member is paid rather than the provider. This arrangement allows members to negotiate with the provider over the billed amount. As a result, the reimbursement amount for the provider on the claim may differ.

UHG recommends that the Allowed Amount Machine Readable File clarify that same time period is applicable to the reporting of allowed amounts and billed charges. In addition, if the implementation date for the machine readable files is not extended, the first report of this data should be made no sooner than July 2022. UHG also recommends CMS make clear that any reimbursement paid directly to a member is excluded from the Unique Out-of-Network Allowed Amount.

The Health Plan Transparency Final Rule required a new machine-readable file for prescription drugs that was not addressed in the Proposed Rule. As a result, stakeholders were not provided an opportunity to consider the proposed disclosures and offer feedback.

In addition, the CAA establishes new reporting requirements for health insurers and group health plans with respect to pharmacy benefits and costs. This provision requires insurers and plans to submit annual reports to the Tri-Agencies with detailed information including:

- The 50 brand prescription drugs most frequently dispensed for claims paid by the plan or insurer.
- The 50 most costly prescription drugs by total annual spending.
- The 50 prescription drugs with the greatest increase in plan expenditures over the plan year.
- Total spending on health care services including costs for prescription drugs.
- Spending for prescription drugs by the health plan or coverage and by enrollees.
- Any impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan, insurer, administrator, or service provider.

The Tri-Agencies are required to make the annual reports publicly available on an internet website with the exception of any confidential or trade secret information. (CAA, Division BB, Title II, Section 204).

UHG recommends CMS work with the Tri-Agencies to remove the requirements to disclose prescription drug information in a separate machine-readable file format as set out in the Health Plan Transparency Rule and the ICRs. Much of this data will be included in the annual report to the Tri-Agencies required by the CAA. If CMS believes information in addition to the CAA mandated disclosures is needed, the Tri-Agencies should publish a proposed rule for a prescription drug machine-readable file allowing sufficient time for stakeholder review and public comment.

UHG recommends CMS work with the Tri-Agencies to remove the requirement to make a prescription drug machine-readable file available to the public. If CMS intends to require reporting of prescription drug data, the requirements should be submitted for public review and comment through the rulemaking process.

The Prescription Drug Machine-Readable File (Appendix 4) requires disclosure of the "historical net price." Inclusion of historical net prices for prescription drugs was not required by the proposed transparency rule and, as a result, any feedback stakeholders might have otherwise provided regarding this data was not addressed in the Final Rule.

The "historical net price" is defined in the Prescription Drug Machine-Readable File format as follows:

> The retrospective average amount paid, reflected as a dollar amount, by a plan or issuer to an in-network provider for the 90-day period beginning 180 days before the file publication date, including any in-network pharmacy or other prescription drug dispenser, for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug or prescription drug service.
>
> The historic net price must be reported at the billing unit level as defined by the NCPDP. The standard contains three units Each "EA," Milliliter "ML," or Gram "GM."8
>
> *Notes on reasonable allocation of rebates, discounts, chargebacks, feeds, and any additional price concessions received by the plan or issuer*:
>
> • If the total amount of the price concession is known to the plan or issuer on the file publication date, then rebates, discounts, chargebacks, fees, and other price concessions must be reasonably allocated by total known dollar amount.
>
> • If the total amount of the price concession is not known to the plan or issuer on the file publication date, then rebates, discounts, chargebacks, fees, and other price concessions should be reasonably allocated using a good faith, reasonable estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period.

As defined, the historical net price of a prescription drug does not provide any value to members. Cost-sharing for prescription drugs is not based upon historical plan costs, rather it is determined using plan negotiated rates or flat dollar copayments, as applicable under their coverage or benefit plan of benefits. Therefore, the inclusion of historical net price does not follow CMS' stated intent of the transparency rule, which is to enable patients to shop for healthcare items and services most efficiently.

Furthermore, disclosure of historical net prices is recognized as having a negative impact on prescription drug costs, as the disclosure can lead to *increased* costs for prescription drugs for insurers and plans and ultimately for members. When confidential pharmaceutical manufacturer drug-level rebate data is made publicly

available, manufacturers have knowledge of competitors' contracted rates, leading to tacit collusion and reducing the level of contracted discounts provided to payers, therefore, increasing net price. The resulting increase in prescription drug costs was recognized by the Federal Trade Commission (FTC) when responding to proposed legislation requiring disclosure of such information:

> [i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors … then tacit collusion among manufacturers is more feasible … Whenever competitors know the actual prices charged by other firms, tacit collusion — and thus higher prices — may be more likely.[1]

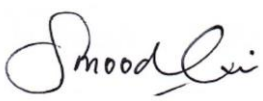
We are concerned that publication of the historical net price will have a negative impact on competition.

UHG recommends the prescription drug machine-readable file not include data related to the historical net prices.

The technical specification for the Prescription Drug Machine-Readable File specifications include three data elements that were not required in the Final Rule: (a) administration fees, (b) transaction fees, and (c) dispensing fees. Based on the final rule definition of historical net price some of these fees are already inclusive in the calculation. This information is beyond the scope of the Final Rule, not needed as separate data elements and should be removed from the file format should the Tri-Agencies retain the requirement to make the prescription drug information available.

UHG recommends that if CMS retains the requirement to produce prescription drug information in a machine-readable file format that the data elements for historical net price, administration fees and transaction fees be removed.

Thank you for your thoughtful consideration of our comments. Should you have any questions, please do not hesitate to contact me.



Sincerely,
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[1] U.S. FTC, Letter to Assembly Member Greg Aghazarian, 2004. Available at https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf.