July 23, 2021

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
Attention: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug
Costs (*CMS-9905-NC*)
200 Constitution Avenue NW, Room N-5653
Washington, DC. 20210

CoverMyMeds appreciates the opportunity to offer comments regarding implementation considerations for data collection applicable to group health plans and health insurance issuers offering group or individual health insurance coverage.

As a part of McKesson Prescription Technology Solutions, CoverMyMeds is a leading medication access company, helping people get the medicine they need to live healthy lives. We help patients navigate medication access throughout their wellness journey through a comprehensive set of benefit and access support solutions such as electronic prior authorization (ePA), Specialty (AMP) and Consumer-Facing Price Transparency.

Since 2008, CoverMyMeds has seamlessly connected the health care network to help reduce prescription abandonment and increase speed to therapy for all patients. CoverMyMeds' network includes more than 75% of all electronic health record systems (EHRs), 50,000+ pharmacies, 750,000 providers and most health plans and PBMs. By facilitating appropriate access to medications, we help customers avoid billions of dollars each year in administrative waste and avoidable medical spending caused by prescription abandonment.

General Comments

CoverMyMeds supports the Departments of Health and Human Services (HHS), Labor and Treasury (the Departments) commitment to address ways and means in which to reduce healthcare costs, increase patient out-of-pocket cost transparency, interoperability, and data fluidity.   These are essential elements to assuring patient choice, reducing cost, reducing provider and patient burden and improving outcomes. HHS, along with the Departments of Treasury and Labor ("Departments"), are empowered to modernize private health coverage with a comprehensive patient information framework. Meaningful progress has been made.

We urge the Departments to complete the important and necessary work started by the passage of recent transparency coverage rules and require all health plans make information available through standards-based (FHIR) APIs and make clear that individuals can authorize any third party, including third-party technology solutions, to access the information on their behalf. These two critical steps will empower patients, remove barriers, alleviate health disparities, and improve health outcomes. The Departments could then evaluate, via reporting, the level of health plan transparency and information sharing via FHIR

API connectivity and the level of improvement of patient access and understanding of their options to obtain their needed care.

The questions asked within this request for information highlight the variances in policy requirements between government, private and public health plans. Our comments below are relative to narrowing those gaps to promote broader healthcare cost transparency.

Specific Comments

Prescription Drug Identification
With respect to prescription drug identification, for decades the healthcare industry has taken advantage of the National Drug Code (NDC) configuration, product and system implementations. Business logic has been built around each of the labeler, product, and package size segments of the NDC. Pharmacy automation, workflow and processing systems are designed to base product selection on the NDC, all of which is communicated to the pharmacy on an electronic prescription using the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard. In fact, the majority of NCPDP standards include the NDC as the primary drug identifier.

The NDC is the key, unique, product identifier used to identify the specific product being prescribed and dispensed and for medication recall purposes. All relate to patient safety. Additionally, within the CMS Transparency in Coverage final rule (*CMS-9915-F*), CMS references commenters' recommendation within this final rule that a more useful unit for drug reporting would be the RxNorm concept unique identifier (RxCUI). In this instance, the commenters suggested using RxCUIs. The commenter further stated that doing so would minimize burden by reducing the list of entries, highlighting the lesser amount of active RxCUIs versus NDCS, and the existing prescription drug machine-readable file requirement for Medicare Part D and QHPs use RxCUIs.
CMS responded to the commenter suggestions with the following points:
- Multiple NDCs can be encompassed by one RxCUI; however, the ***accuracy of pricing information*** requires precise and specific product information, including package size and manufacturer.
- Replacement of NDCs by RxCUIs would lead to inaccurate or misleading information being provided to the consumer. If RxCUI is used within the machine-readable files, then plans and issuers may not be able to provide the manufacturer negotiated rate, especially for those RxCUIs that include NDCs from several manufacturers.
- NDCs are more generally used by the Part D and QHP programs when information is required to be submitted to CMS for payment programs, not RxCUIs.
- The NDC is a standard billing code required for prescription drug transactions and should remain.

Therefore, it is our recommendation that the Departments and OPM also support identifying prescription drugs by NDCs.

Reporting and The Role of Pharmacy Benefit Managers (PBMs)
PBM market segmentation covers specialty pharmacy services, benefit plan design and administration, pharmacy claims processing, formulary management, and more. Given this positioning and the data that flows through PBMs, they could play a significant role in furnishing necessary information to plans and issuers, or the Departments, if required. There is also an opportunity to expand the information required to be reported to include additional statistics that would be of value to the Departments and OPM in their analysis and for inclusion within public reports, as well as to the overall healthcare industry and operations.

With prescription drug cost transparency at the forefront of this request and an overall policy and industry focus on improving health equity and disparities in healthcare, the Departments and OPM should consider including the following points as information to be reported by group health plans and health insurance issuers and/or PBMs.

- The extent to which the top 50 medications being reported are tied to a non-accumulation program.
- The rate at which the top 50 medications that are required to be reported transitioned from coverage under a patient's medical benefit to the pharmacy benefit.
- The number of participants, beneficiaries, and enrollees covered by the plan, issuer that are part of coordinated or value-based care arrangements.
- The number and types of therapies included in value-based arrangements.

This type of information, specifically relative to non-accumulation programs, would assist manufacturers in complying with government price reporting requirements as set forth in the CMS *Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid* (*CMS-2482-F*) final rule.

- The final rule references commenter concern that manufacturers may not currently have the ability to track their manufacturer assistance to ensure it is provided in full to the patient.
- CMS responded that the electronic prescription claims processing infrastructure currently in place can serve as a possible foundation for manufacturers to have the ability to ensure their manufacturer-sponsored assistance is going to the patient, adding that manufacturers currently contract with pharmacy switches and brokers that are electronically connected to this prescription claims processing system.
- CMS noted that manufacturers have relationships with PBMs, given that they pay rebates and other price concessions for formulary placement on the PBMs' formularies, and that electronic and contractual infrastructure is in place for manufacturers to better understand how the PBMs are using the manufacturer assistance.
- CMS adds that there is an expectation that PBMs will work with manufacturers to provide this information to the manufactures to help them ensure that their assistance is passed through to the patient.

The Departments and OPM should consider CMS' positioning, as referenced above, within the data elements proposed to be reported by plans, issuers, and PBMs within this rulemaking.

Leveraging Technology Advancement and Application Programming Interfaces (APIs) Use within Reporting Requirements

Overall healthcare industry focus including policy continues to trend on matters of interoperability, transparency, and patient access of their healthcare data. Rulemaking such as the CMS *Transparency in Coverage* (*CMS-9915-F*) final rule, the CMS *Interoperability and Patient Access* (*CMS-9115-F*) final rule on APIs, and more speak to current and future requirements on plans, issuers and PBMs to make data available to patients in relation to their healthcare costs by leveraging the use of technology such as APIs.

With respect to the recent API requirements, we recommend that the Departments and OPM consider requiring plans, issuers, and PBMs to report on the use and capabilities of their APIs. More specifically, plans, issuers, and PBMs should provide statistics relative to the following data points.

- The number of APIs that are available by plans and PBMs, as well as the connectivity to those APIs.
- The type of date shared by the plan and/or PBM within the API.

- The rate at which there is denied access to the API.

Broadening reporting requirements within this policy, to align with the technology capabilities and data elements required to be shared via APIs, will give insight into the level of adoption of said technologies, confirm how APIs are or are not advancing patient access to their needed care, validate if this technology is reducing provider and patient burden, improve interoperability amongst healthcare stakeholders and reduce instances of information blocking.

Conclusion
CoverMyMeds continues to support the Departments' commitment to promoting greater price transparency in healthcare and creating pathways via regulatory action to promote competition and bring down overall costs to the consumer. We believe that continued focus on increasing patient transparency to the options available to them and their out-of-pocket costs for said access, interoperability and data fluidity are all areas that will continue to create change and value for patients and the whole of the healthcare ecosystem. We encourage your continued focus in these areas and are happy to be a resource to the Departments in these endeavors.

If you have questions, please contact Kim Diehl-Boyd, Vice President, Industry Relations and Government Affairs, at kdiehlboyd@covermymeds.com or 615-663-5579.

Thank you,

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