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October 12, 2015

VIA ELECTRONIC FILING – via regulations.gov

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS–10572 Transparency in Coverage Reporting by Qualified Health Plan Issuers, OMB control number: 0938-New

Dear Mr. Slavitt:

We write on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) to comment on the proposed collection of information for Transparency in Coverage Reporting by Qualified Health Plan Issuers. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $51.2 billion in 2014 alone.

Data collection is crucial to understanding, evaluating, and ultimately improving the coverage offered through the health insurance exchanges. Given the importance of data collection, we were disappointed to see that the proposed collection of information is limited to only basic plan information that is largely already available and does not include new data requests that would provide insight into how beneficiaries are accessing care. PhRMA previously submitted a letter to Kevin Counihan at Center for Consumer Information and Insurance Oversight regarding the potential for section 1311(e)(3) of the Affordable Care Act to be used to enhance understanding of how beneficiaries interact with their health insurance and identify potential access barriers (see Attachment A). We are resubmitting these comments to urge the

Centers for Medicare & Medicaid Services to reconsider the proposed collection of information in favor of including the requests described in the attached letter, which would provide additional data that would be valuable to regulators, consumers and researchers.

Sincerely,

/s/

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Karyn Schwartz
Deputy Vice President, Policy & Research

Attachment A

PhRMA
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July 27, 2015

VIA EMAIL: Kevin.Counihan@cms.hhs.gov

Mr. Kevin Counihan
Director & Marketplace Chief Executive Officer
Center for Consumer Information and Insurance Oversight
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Data collection under Section 1311(e)(3) of the Affordable Care Act.

Dear Mr. Counihan:

We write on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) in follow-up to the final Notice of Benefits and Payment Parameters, which indicated the Department of Health and Human Services (HHS) intends to solicit comments related to data collection under section 1311(e)(3) of the Affordable Care Act prior to implementing the data collection. This letter expands on our previous comments regarding section 1311(e)(3), which were submitted as part of our Notice of Benefits and Payment Parameters comment letter. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $550 billion in the search for new treatments and cures, including an estimated $51.1 billion in 2013 alone.

Data collection is crucial to understanding, evaluating, and ultimately improving the coverage offered through the health insurance exchanges. Publicly available data can enhance understanding of how people interact with health insurance and the health care system and is useful in identifying potential access barriers or other areas of concern. Data also will prove enormously useful to state Departments of Insurance and may help them identify plan outliers for

further regulatory review. Given the limited resources of many Departments of Insurance, it would be beneficial to help them target plan reviews and use their staff's time efficiently.

In order to allow researchers and other data users to make connections between plan design and the data suggested in this letter, the data files that are publicly available should include information on plan design (e.g., cost sharing, type of network) that is included in the Summary of Benefits and Coverage. It should also be easily linkable to the data provided in machine-readable formulary files required to be provided by issuers in the federal Exchange and in the Landscape files provided by Healthcare.gov, as well as similar files provided by state Exchanges.[1]

We understand based on the final Notice of Benefits and Payment Parameters that some commenters suggested that HHS only collect data that would be useful to consumers as they select a qualified health plan (QHP). PhRMA feels strongly that this should not be the only criterion for deciding which data elements to collect. A more comprehensive data collection effort will go a long way towards providing consumer groups, researchers and journalists with policy-relevant information about QHPs and how consumers are accessing care once enrolled in coverage.

Below we suggest a number of data elements that would help identify outliers and flag plan behavior that might have negative health implications for beneficiaries. Researchers also could use the data to look for relationships between specific aspects of plan design and access challenges. Without robust data collection and oversight, plans may be continually approved for participation as QHPs despite engaging in outlier practices that unfairly limit access to needed medicines. While consumers themselves may not be able to easily interpret all of the information we recommend collecting, it is all relevant to consumers' ability to access services and therefore should be collected and shared in a format that can be analyzed by third parties.

We suggest the following metrics be considered for collection under 1311(e)(3):

1. *Plan justifications.* To the extent that plans are filing justifications when they do not meet minimum standards under Essential Health Benefit (EHB) rules, both the fact that a plan filed a justification and the justification itself should be publicly available. This would allow consumer groups to flag a plan that does not meet quantitative standards for EHB and will allow researchers to analyze the justifications and whether they are associated with differences in plan quality. This information also will be relevant, when reviewed in tandem with the other data we are suggesting, to evaluate whether allowing plans to fall below EHB standards is impacting access.

[1] Healthcare.gov, "Health and dental plan datasets for researchers and issuers," Available at: https://www.healthcare.gov/health-and-dental-plan-datasets-for-researchers-and-issuers/ (accessed May 21, 2015).

2. *Exception claims upheld and overturned*. Plans should report data on the share of beneficiaries seeking an exception for coverage of a non-formulary drug and the rate at which those exceptions are granted or denied. Additionally, plans should report on the drug classes (using the most recent U.S. Pharmacopeial Convention Medicare Model Guidelines) that most commonly include medicines subject to exceptions. Data should be broken out by standard and expedited review and by internal and external review. These data could be used to flag plans that omit widely used medicines or medicines where therapeutic substitutes are not available.

3. *Rates of prescription reversals.* Prescription reversals happen when a pharmacy fills a prescription but the patient never picks up the medicine. This can happen for a variety of reasons, including cost sharing levels that a patient cannot afford or when a patient decides that she no longer needs or wants the medicine. Plans should report the share of prescriptions reversed by pharmacies over a standard specified period, as well as the share of enrollees for whom one or more prescriptions were reversed within a coverage year. Plans should also report the classes of medicines more likely to be subject to reversals, using the same classification system used for enforcing Essential Health Benefits.

   Timely data on prescription reversals would help consumer groups and researchers identify plans and plan benefit design characteristics that may discourage appropriate use of medicines. High out-of-pocket costs or formulary restrictions can have negative impacts on medication initiation and adherence.[2] There may be other plan design policies impacting prescription reversals as well. For example, the design of preferred pharmacy networks could also have an impact. Looking at plans with relatively high rates of prescription reversals could help identify plan benefit or network designs that might be negatively impacting appropriate use of medicines. Release of these data are essential to exploring the extent to which patients fail to fill recommended prescriptions, correlations with plan characteristics, and implications for adherence, clinical outcomes, and spending.

   Data on reversals should be reported to regulators on a quarterly basis, potentially with a one quarter lag. These data should be reported both as aggregated for all plan enrollees and then also separately reported for enrollees in cost-sharing reduction plans.

4. *Rates of prescription rejections.* Plans should report the share of rejected prescriptions over a standard, specified period, as well as the share of enrollees with one or more prescriptions

[2] Goldman D et al., ―Pharmacy Benefits and the Use of Drugs by the Chronically Ill,‖ *JAMA*, May 19, 2004, 291(19):2344-2350; Shrank WH, Choudhry NK, Fischer MA, Avorn J, Powell M, Schneeweiss S, Liberman JN, Dollear T, Brennan TA, Brookhart MA, ―The Epidemiology of Prescriptions Abandoned at the Pharmacy,‖ *Ann Intern Med*. 2010 Nov 16;153(10):633-40; Blesser Streeter S, Schwartzberg L, Husain N, and Johnsrud M, ―Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions.‖ *Journal of Oncology Practice*7(3s) (2011): 46s–51s.; Tamblyn R, Eguale T, Huang A, Winslade N, Doran P. The Incidence and Determinants of Primary Nonadherence With Prescribed Medication in Primary Care: A Cohort Study. Ann Intern Med. 2014;160:441-450. doi:10.7326/M13-1705

rejected. Prescriptions are rejected when an insurer refuses to pay a pharmacy claim, often because the medicine is not on the formulary or is subject to prior authorization or step therapy. Plans should also report the classes of medicines more likely to be subject to rejections, using the same classification system used for enforcing Essential Health Benefits.

Relatively high rates of rejections could help regulators identify potentially discriminatory use of prior authorization or step therapy. It could also point to transparency challenges that may make it more difficult for patients and their doctors to understand exactly which medicines will be covered. Release of these data are also essential to exploring the extent to which patients fail to fill recommended prescriptions, correlations with plan characteristics, and implications on adherence, clinical outcomes, and spending. This data should be reported both as aggregated for all plan enrollees and then also separately reported for enrollees in cost-sharing reduction plans.

If possible, plans should also report the share of prescription rejections that are for patients who had previously been taking a therapy covered by their insurer that was later rejected due to a change in the insurer's formulary. Identifying outliers using this data would help identify plans that may be frequently changing their formulary in a way that requires stable patients to switch to a new medicine for non-clinical reasons.

5. *Prior Authorization.* Issuers should be required to report the number of pharmacy transactions rejected due to prior authorization. Additionally, issuers should have to report the number of favorable prior authorization decisions. At a minimum, this data should be reported for each QHP an issuer offers. Medicare Part D already requires that plans report this data and it provides useful data for both regulators and researchers.

   If possible, it would be informative to also have plans report this data by United States Pharmacopeia (USP) class. CMS has already noted that prior authorization requirements can potentially be used to discriminate against certain types of patients.[3] In order to identify potentially discriminatory plans, CMS stated in the Letter to Issuers that it will "perform an outlier analysis to identify QHPs that are outliers based on an unusually large number of drugs subject to prior authorization and/or step therapy requirements in a particular USP category and class."[4] The additional data suggested here will provide CMS, researchers and states with additional data on prior authorization. This data could help identify plans that are subjecting certain classes of medicines to overly arduous prior authorization standards. Without this additional data, CMS is limited to analyzing only the presence of prior authorization standards and will not have any data to suggest whether the prior authorization approval criteria are permitting appropriate use of medicines.

[3] CMS, "FINAL 2016 Letter to Issuers in the Federally-facilitated Marketplaces," February 20, 2015, page 40.
[4] Ibid.

6. *Adherence to therapy.* Past studies show that a significant share of individuals insured in the commercial market whose drug is rejected due to prior authorization, step therapy, or a formulary exclusion end up not filling any prescriptions rather than switching to a different drug.[5] It would be valuable to see if this is occurring in the exchange market as well. In order to address any transition issues that may arise and ensure beneficiaries continue to receive appropriate treatment, plans should report the share of enrollees with a rejected prescription who do not fill a prescription for an alternative therapy within a 60-day window. These data should be reported both as aggregated for all plan enrollees and then also separately reported for enrollees in cost-sharing reduction plans.

7. *Consideration of newly approved medicines.* Plans should report (a) the percent of newly approved medicines that are reviewed by a pharmacy and therapeutics (P&T) within 90 days, and (b) the percent of medicines for which the plan has made a coverage decision within 180 days. These data requests would assess compliance with the requirements for review of new medicines in the 2016 Notice of Benefit and Payment Parameters, which take effect for the 2017 plan year.[6] This requirement was added to ensure that formularies were updated during the year to reflect medical advances. By requesting data on both the timeframes under which new medicines are reviewed and the approval rate for new medicines, HHS will be better able to identify plans that are slow to evaluate new medical innovations and can track whether the new P&T requirements are sufficient to provide patients with the assurance that they will be able to benefit from newly approved medicines.

8. *Distribution of spending.* Plans should report the share of enrollees who reach the plan's out-of-pocket maximum in each month for enrollees who are continuously enrolled throughout the year. These data should be reported both as aggregated for all plan enrollees and then also separately reported for enrollees in cost-sharing reduction plans.

   Data on the rate at which beneficiaries reach their out-of-pocket maximum will help researchers understand overall spending patterns. The data will illustrate the association between plan design and the distribution of out-of-pocket and total spending over time. Silver and bronze plans with fewer beneficiaries reaching their out-of-pocket maximum may be doing a better job of allowing people to spread costs out throughout the year than plans with greater cost sharing or deductibles up front. Having this data stratified by receipt of cost-sharing reduction subsidies will help gauge how those subsidies are working.

[5] Zeng, F. "Impact of Rejected SGA Claims on Persistence to Antipsychotic Medications," *The American Journal of Pharmacy Benefits*, March/April 2012; Gleason, P. "Assessing Step-Therapy Programs: A Step in the Right Direction," *Journal of Managed Care Pharmacy*, April 2007.
[6] Fed. Reg. Vol 80 No 39.

9. *Prevalence of higher spending.* For enrollees continuously enrolled throughout the year, plans should report what share of enrollees spend more than $500, $1,000 and $2,000 out of pocket in any given month. These data should be separately reported for enrollees in cost-sharing reduction plans.

   Past research has noted that when medical spending is highly concentrated, it can create significant financial pressure for families.[7] Additionally, studies have shown that many individuals have relatively low levels of liquid assets available, which could make it difficult for them to pay $1,000 or more towards their medical care at one time.[8] In fact, a recent Federal Reserve survey found that about half of adults do not have $400 to cover an emergency expense without borrowing.[9] Making available this data on out-of-pocket spending will allow researchers to analyze which types of plan designs are most likely to lead to these high levels of spending. The data may also help identify plans with benefit designs that federal and state regulators should be reviewing more closely. Having this data broken out separately for individuals receiving cost-sharing reduction subsidies will help gauge how those subsidies are working and whether additional rules are necessary to prevent high cost sharing for the lowest income marketplace consumers.

10. *Use of Alternative Payment Models.* HHS has expressed interest through its Health Care Payment Learning and Action Network in working with the private sector to further its goal of transitioning to a value-based health care system. Consistent with this goal, plans should report information on the types of alternative payment models (APMs) that they are implementing in their networks (e.g., accountable care organizations, bundled payments, patient-centered medical homes, and similar models) and the proportion of providers participating in these arrangements. We note that HHS will collect similar information from Medicare Advantage plans beginning this year in order to test and evaluate new payment models more effectively.[10] Data on how these arrangements are being used by QHPs will facilitate shared learning and maximize the ability for researchers and regulators to understand, assess, and compare APMs and their impact on patient care.

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[7] Selden T "The Within-Year Concentration of Medical Care: Implications for Family Out-of-Pocket Expenditure Burdens," *Health Serv Res*. 2009 Jun; 44(3): 1029–1051.
[8] Kaiser Family Foundation, *Medical Debt among People with Health Insurance*, January 2014; Corporation for Enterprise Development, Excluded from the Financial Mainstream: How the Economic Recovery is Bypassing Millions of Americans, January 2015.
[9] U.S. Federal Reserve Board of Governors, *Report on the Economic Well-Being of U.S. Households in 2013 July 2014*, July 2014.
[10] Center for Medicare and Medicaid Services. "Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter," February 20, 2015, 114.

We thank you for the opportunity to share our recommendations regarding data collection for QHPs under section 1311(e)(3), and note that many of these items also could be collected from a wider variety of plans under section 2715A of the ACA. If you have any questions about any of our recommendations, please contact Karyn Schwartz at 202-835-3491 or kschwartz@phrma.org.

Sincerely,

/s/

Karyn Schwartz
Deputy Vice President, Policy & Research

/s/

Lisa Joldersma
Vice President, Policy & Research
Public Programs

/s/

Sylvia Yu
Assistant General Counsel