December 22, 2014

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue SW.
Washington, DC 20201

Re: [Docket No. CMS-9944-P] Notice of Benefit and Payment Parameters for 2016

Dear Sir/Madam:

On behalf of the National Community Pharmacists Association (NCPA) I would like to submit the following comments and suggestions in response to the proposed Notice of Benefit and Payment Parameters for 2016.

The National Community Pharmacists Association (NCPA) represents the interests of America's community pharmacists, including the owners of nearly 23,000 independent community pharmacies. Together they represent an $88.8 billion health care marketplace, dispense nearly 40% of all retail prescriptions, and employ more than 300,000 individuals, including over 62,000 pharmacists.

Specifically, NCPA would like to offer specific suggestions in the areas of prescription drug coverage, drug formularies, access requirements and network adequacy.

Section 156.122 Prescription Drug Benefits

Current Essential Health Benefit (EHB) rules require that an insurer's drug formulary list cover the greater of at least one drug from each United States Pharmacopeia (USP) class or category or the same number of drugs for each USP class or category as are covered by the state's benchmark plan. The proposed rules offers two alternatives: requiring EHB Plans adopt a pharmacy and therapeutics (P&T) committee to ensure that the plan's formulary drug list covers a sufficient number and type of prescription drugs, or replacing the USP standard with a standard based on the American Hospital Formulary Service (AHFS) drug classification system.

P&T committees are not new, they have been used by health systems and health plans, and CMS and the National Association of Insurance Commissioners (NAIC) have defined standards for such committees to ensure transparency and consumer protections. The AHFS classification is updated annually, with more classifications than the USP guidelines. In 2005, CMS adopted

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the AHFS as the only named alternative to the USP for use by PDPs in Part D drug formularies, so insurers are already familiar with it, and could transition to it from the USP system.

In March 2013, the HHS Office of Inspector General issued a report that expressed concerns over CMS's lack of oversight of P&T committee conflicts of interest in Medicare Part D. As the entities responsible for making Medicare Part D formulary decisions, P&T committees must ensure that their decisions are made based on scientific evidence and not based on the personal financial interests of committee members, but the OIG identified several issues: limited definitions of conflict of interest, committee members allowed to determine and manage conflicts of interest and inadequate oversight of P&T committee conflict of interest compliance. Additionally, during 2010 CMS did not have audit protocols to audit P&T committee member conflicts of interest. In 2012, CMS added an optional review of P&T committee documentation to determine compliance with federal conflict of interest requirements, but less than 10 percent of its audits included these elements.

If CMS ultimately decides to require health plans to establish P&T committees to develop drug formularies, NCPA would support following the 2013 OIG recommendations:

•Specify that P&T Committee conflict of interest requirements extend to Pharmacy Benefit Managers (PBMs), which are not specifically named by CMS in P&T committee requirements (only sponsors and pharmaceutical manufacturers are) but can benefit financially from plan formulary decisions by retaining a percentage of price concessions negotiated with pharmaceutical manufacturers on behalf of sponsors;
•Require sponsors to maintain policies and safeguards applicable to P&T committee members who are employed by the entity that maintains the committee;
•Require sponsors to use objective processes to determine if P&T committee members' disclosed financial interests do in fact constitute a conflict of interest;
•Require sponsors to use objective processes to manage disclosed P&T committee members' conflicts of interest, including specifying when the member must be recused from discussion and/or voting; and
•Oversee compliance with P&T conflict of interest procedures, including auditing both plan sponsor P&T Committee conflict of interest determinations and management policies.

NCPA suggests that CMS adopt a P&T committee approach with a minimum drug count requirement based on either the USP or AHFS classification as a benchmark. Because states and insurers are more familiar with the USP standard, having used to develop formularies in 2014 and 2015, we would further suggest that any change not be implemented prior to the 2017 plan year.

Section 156.122(d) Formulary Drug Lists

NCPA generally supports the proposed rule that health plans publish up-to-date, accurate and complete list of all covered drugs on its formulary list and in a manner that is easily accessible.

Inclusion of formulary tiering information and cost sharing information would improve transparency for enrollees and potentially reduce out-of-pocket spending.

NCPA is concerned, however, with the proposed requirement that issuers make formulary lists "publicly available on their websites in a machine-readable file and format specified by HHS" to provide the opportunity for third parties to create resources that aggregate information on different plans. Is the intention to establish a web portal similar to Plan Finder in the Part D program? Without clear marketing standards, we are concerned about the potential of information being shared with third parties that may engage in misleading marketing, or efforts to steer patients to plan options that do not best meet their needs.

Section 156.122(e) Mail Order

NCPA supports the proposed revision of §156.22(e) to add new requirements to the EHB prescription drug definition requiring enrollees to be provided with the option to access their prescription drug benefit through retail pharmacies, and not be forced by issuers to use mail order services exclusively. NCPA also strongly supports CMS's view that "making drugs available only by mail order constitutes fulfilling the obligation under the Affordable Care Act to provide prescription drug coverage as part of EHB" and "making drugs available only by mail order would discourage enrollment by, and thus discriminate against, transient individuals and certain individuals who have conditions that they wish to keep confidential."

We strongly support the proposed requirement to the EHB prescription drug definition to require that enrollees be provided with the option to access their prescription drug benefit through retail (bricks and mortar or non-mail order pharmacies) and that plans cannot have a mail order only prescription drug benefit. The proposed rule would still allow a health plan to charge a higher cost-sharing amount when obtaining the drug at an in-network retail pharmacy than he or she would pay for obtaining the same covered drug at a mail order pharmacy. However, NCPA strongly supports the proposed accompanying proviso that provides that the additional cost sharing for the covered drug would count towards the plan's annual limitation on cost sharing under Section 156.135 and would need to be taken into account when calculating the actuarial value of the health plan under 156.135.

In addition, we would like to propose that an additional provision be included that would allow a retail pharmacy to charge the same copay as the mail order pharmacy as long as the retail pharmacy agrees to accept the same reimbursement as the mail order pharmacy. Additionally, we request that CMS adopt the requirement that plans offering 90 day drug fills at mail order network pharmacies must also offer 90 day drug fills at retail network pharmacies. Many times, retail pharmacies are more than willing to accept the same reimbursement as the mail order pharmacy but the plan design does not allow them to do so and in turn mandates that they charge a higher co-pay. In light of the fact that many PBMs own their own mail order pharmacies and are largely responsible for prescription drug benefit plan designs, they have a vested financial interest in establishing plan benefit designs that unfairly advantage their own mail order pharmacies. To level the playing field between mail order pharmacies and bricks

and mortar pharmacies and to provide plan beneficiaries with a true choice in where to access their prescription drugs that does not financially disadvantage the plan, we strongly encourage the addition of these provisions.

Specialty Drugs

On the topic of the provision of "specialty drugs" or the restriction of access to certain Part D drugs to only certain pharmacies, NCPA recommends that the agency adopt the stated policy of CMS in its administration of the Medicare Part D program. CMS has already provided regulatory guidance on this very issue for Part D plans (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess_051706.pdf). According to the agency's own FAQ:

"Part D plans may not restrict access to certain Part D drugs to "specialty" pharmacies within their Part D network in such a manner that contravenes the convenient access protections of §1860D-4(b)(1)(C) of the Social Security Act and 42 CFR §423.120(a).

Specifically, Part D plans may not restrict access to Part D drugs by limiting distribution through a subset of network pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy. Therefore, Part D plans may not restrict access based solely on the placement of a Part D drug in a "specialty/high cost" tier because this tier placement alone is not indicative of any special requirements associated with such drug."

The CMS guidance allows Part D plans to specify, on a drug by drug basis, reasonable requirements for network pharmacies to ensure appropriate handling and dispensing of a particular Part D drug that requires special attention. These drug by drug requirements should only apply to special handling and dispensing that may be required for a particular "specialty" drug and not to reimbursement or other standard contracting terms and conditions. Requiring pharmacies to accept different reimbursement rates for certain "specialty" drugs is inconsistent with standard industry practice, could result in plans setting reimbursement rates below the market rates set in their standard contracts, and could be used to subvert the convenient access standards.

NCPA strongly recommends that CMS extend this guidance to qualified health plans (QHPs), specifically the provision that "Part D plans may not require network pharmacies to qualify as a "specialty" pharmacy in order to dispense any drug that requires special attention if the network pharmacy is capable of appropriately dispensing the particular Part D drug or drugs in question." The convenient access standards dictate that "specialty" pharmacies be used to supplement network pharmacy access when necessary and not otherwise restrict it.

NCPA seeks clarification that the FDA alone makes the determination that retail pharmacy cannot provide specialty services, and not the plan or a PBM. We would suggest that the exception should read that a drug can be offered solely through mail where "the FDA has determined that the drug requires special handling, provider coordination or patient education that cannot be provided at a retail pharmacy" so as to prevent plans from shifting a large number of drugs to mail order.

Finally, the Office of Personnel Management now requires any drugs in tier 3 (non-formulary brand drugs) or tier 4 (specialty drugs) of the Federal Employee Health Benefits (FEBH) plan to be dispensed solely via mail order. NCPA has consistently objected to forced mail order and would encourage CMS to explicitly prohibit QHBs from arbitrarily tiering specialty medications for the purposes of requiring mandatory mail order.

Section 156.230 Network Adequacy Standards

Since the passage of the Affordable Care Act (ACA), and in preparation for the market reforms that took effect this year, insurers have used network design to lower costs. The use of narrower networks as a mechanism to reduce premiums is not new, and it is not limited to plans in the new marketplaces. Many insurers have responded to the ACA's requirements and evolving marketplace by offering health plans with lower premiums in exchange for more limited access to health care providers. There has been vocal consumer backlash in response to these narrow networks. The California Department of Managed Health Care alone has reported receiving more than 200 complaints from patients having difficulty getting access to a healthcare provider.

State regulators in California recently found that 12.5 percent of the physicians listed in the Anthem Blue Cross provider directory for exchange plans had inaccurate locations and 13 percent did not take patients who had Anthem's exchange plans even though they were listed as in-network. The state's investigation of Blue Shield found that 18.2 percent of doctors in the plan directory were not located where the insurer said they were, and 9 percent of doctors were not willing to accept patients who had Blue Shield's Covered California plans. We applaud CMS for proposing a new requirement §156.230(b) that QHPs update provider directories monthly and make that information easily accessible to enrollees and prospective enrollees.

The issue of network adequacy is crucial for consumers and the health care delivery system itself. Adequate access to pharmacy care services and prescription medications are critical to stave off costly downstream medical interventions. While access to health insurance is critical—there must also be an adequate number of providers to serve these new patients in order for the health coverage to be meaningful. In addition, it is important to remember that the insurance marketplaces are going to be utilized mainly by a demographic that has had little or no access to health insurance, and in turn, access to health care services or prescription drug therapies. Therefore, this is a population that is likely to need a myriad of services immediately upon obtaining coverage. This is especially critical with regard to access to pharmacy care services.

The New England Healthcare Institute (NEHI) has estimated that medication-related problems including poor adherence impose as much as $290 billion in annual costs, or 14 percent of healthcare expenditures. These costs include emergency room visits, hospitalizations, and other preventable forms of care. Ensuring adequate access to prescription medications can stave off many of these costly downstream interventions and provide an excellent return on investment.

A recent study by Avalere Health found that "the evidence around pharmacists' impact on clinical and economic outcomes is growing, and overall, points to improving therapeutic outcomes and reducing costs," and notes that "continued research that clearly reports the specific pharmacist services … and the impact these services have on outcomes and healthcare costs" can help to further inform policymakers and healthcare providers. This is especially true as the healthcare environment continues to evolve with the advent and rise of new collaborative care models of delivery such as patient-centered medical homes and Accountable Care Organizations (ACOs).

NCPA Strongly Recommends the Use of the TRICARE Retail Pharmacy Access Standards In Order to Ensure Sufficient Beneficiary Access to Pharmacy Care Services

Under the Department of Defense TRICARE program, prescription drug benefit plans are required to secure the participation of a sufficient number of pharmacies (not including mail service) in their pharmacy networks to ensure convenient beneficiary access. These standards require a certain percentage of beneficiaries to live within a certain number of miles of a retail pharmacy based on whether they reside in an urban, suburban or rural area. In urban areas, at least 90% of beneficiaries on average must live within two miles of a participating retail pharmacy; in suburban areas, at least 90% of beneficiaries on average must live within five miles of a participating retail pharmacy; and in rural areas, at least 70% of beneficiaries on average must live within fifteen miles of a participating retail pharmacy.

In addition, under current Medicare Part D standards, pharmacy networks must be at least as inclusive as those recognized under the TRICARE program. Part D and the TRICARE program recognize the fact that adequate access to retail pharmacy services are essential and must be evaluated based on the beneficiaries location in either an urban, suburban or rural areas. Ideally, Exchanges should allow all pharmacies that wish to participate be included in the network and consider the TRICARE/Part D retail pharmacy access requirements as a minimum threshold for network adequacy. In addition, we recommend that the TRICARE retail access standards be applicable to all pharmacy networks—and should not permit the exclusion of any "preferred pharmacy networks" similar to what currently exists in Part D due to the recent findings of a CMS access study of these networks.

NCPA would also recommend that the marketplaces create specific standards under which QHP issuers must establish an on-going monitoring process to ensure the sufficiency of the network for enrollees. Such a monitoring program could include regular beneficiary surveys and should

also require QHPs to implement certain remedial measures in order to boost beneficiary access if a network is found to be too restrictive.

Recent CMS Study on Impact of Preferred Pharmacy Networks in Part D Indicate Problems with Convenient Patient Access

In response to concerns about beneficiary access to, and understanding of, preferred cost sharing arrangements, CMS agreed to study the issue, and on December 16, released findings from its *Analysis on Preferred Cost-Sharing Pharmacy Networks,* concluding that the results "reinforce CMS' concern that plans are offering access to pharmacies with lower cost-sharing in a way that may be misleading to beneficiaries, in violation of CMS requirements." NCPA believes that, similar to Medicare Part D and other government-funded programs, minimum pharmacy access standards should be required of all plans operating in the exchanges.

NCPA Supports Recommendation for Transitional Care

NCPA supports the agency's recommendation that qualified health plan (QHP) issuers offer new enrollees transitional care for an ongoing course of treatment for 30 days following the effective date of coverage. Plans will have different provider networks, and consumers may not always be aware of their provider's inclusion in the network, or able to switch providers if they are undergoing a course of treatment with a provider that is not in the new issuer's network. In such a case, it may take time for the new enrollee to select a new in-network provider and to meet with the new provider to ensure that there is no disruption in treatment.

NCPA greatly appreciates the opportunity to provide these comments and suggestions.

Sincerely,

Susan Pilch
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