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Centers for Medicare & Medicaid Services
Room 445-G, Hubert Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

February 25, 2014

Re: Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces

Dear Ms. Tavenner:

Thank you very much for this opportunity to submit the following comments on the "Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces" (the "Draft Letter") issued by the Centers for Medicare & Medicaid Services (CMS) on February 4, 2014.[1] We, the undersigned organizations, are committed to expanding access to immunizations for the entire population—including individuals enrolled in qualified health plans (QHPs) through the Federally-facilitated Marketplace (FFM)—as well as achieving the Healthy People 2020 goals for immunization.

One of the most important provisions of the Affordable Care Act (ACA) was the establishment of the "immunization coverage standard," which requires plans to cover immunizations recommended by the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) without cost-sharing when administered by an in-network provider. As we are beginning to see, thanks to the ACA, many formerly uninsured individuals are now able to purchase more affordable health insurance through the health insurance Marketplaces and thus, for the first time, can access the medical care and preventive services they need. We firmly believe that, to fulfill the goals of the ACA, the standards for the QHPs that are made available through these Marketplaces must ensure meaningful coverage for medically necessary care, including the benefits promised under the ACA. This includes not only the Essential Health Benefits, but also the preventive services—including immunizations—that virtually all plans must cover without cost-sharing.

While we applaud CMS's efforts to provide additional operational and technical details to issuers of QHPs through the Draft Letter and other guidance, we still have concerns that the standards and review procedures described in the Draft Letter may leave enrollees without access to critical immunization services, contrary to the intent of the ACA. In particular:

- While we understand and support the continued role for states in the regulation of health insurance, there is a critical need for CMS to ensure QHP compliance with the

[1] Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services, Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces (Feb. 4, 2014), available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/draft-issuer-letter-2-4-2014.pdf.

ACA's "immunization coverage standard," as this requirement is inextricably intertwined with the QHP-specific requirements related to network adequacy;

- In reviewing the adequacy of QHP provider networks under the new "reasonable access" standard, in addition to those areas "which have historically raised network adequacy concerns," such as primary care providers, CMS should ensure that QHPs include in their networks those provider types that furnish benefits promised under the ACA—including ACIP-recommended immunizations;
- CMS should refine the applicable Essential Community Provider (ECP) standards by requiring QHPs to include in their networks all types of complementary immunization providers (i.e., pharmacy, public health department clinic, school-based clinic, or other community site) in each county in the service area; and
- CMS should stipulate that all ACIP-recommended immunizations, whether provided in- or out-of-network, are covered and exempt from cost-sharing requirements, either in the revised 2015 Letter to Issuers or in the regulations currently under development by the Agency.

Each of these comments is discussed in greater detail, below.

I. CMS Should Ensure Compliance With the ACA's "Immunization Coverage Standard," as It Is Inextricably Intertwined with the Law's QHP-Specific Network Adequacy Requirements (Ch. 1)

As CMS recognizes in the Draft Letter, "[s]tates are the primary regulators of health insurers."[2] Accordingly the Agency leaves the states solely "responsible for enforcing the market reform provisions in title XXVII of the Public Health Service (PHS) Act both inside and outside the marketplaces."[3] While we strongly support CMS's acknowledgement of the critical role of states in regulating health insurance, we also believe that CMS has a key responsibility in this area. Indeed, some of the more generally applicable insurance reforms under title XXVII of the PHS Act are so inextricably intertwined with the ACA's QHP-specific requirements that oversight for these obligations cannot be segregated in the way that CMS proposes.

Take, for instance, the ACA's "immunization coverage standard" (i.e., the requirement that plans cover all ACIP-recommended immunizations, with zero cost-sharing, per section 2713 of the Public Health Service Act).[4] This obligation is a key way by which the ACA achieves one of its principal aims: ensuring broad access to a critical set of preventive services for all privately insured individuals. Yet, this critical provision cannot be effectuated unless health plans have sufficiently robust provider networks that include immunization providers. This is because, as you are no doubt aware, the requirement to cover immunization services with no cost-sharing applies only with respect to in-network providers.[5] Therefore, to the extent

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2 Supra note 1 at 6, n. 2.

3 Id.

4 42 U.S.C. §§ 300gg-13.

5 See 45 C.F.R. 147.130(a)(3) ("Nothing in this section requires a plan or issuer that has a network of provider to provide benefits for items and services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.").

a provider is excluded from a plan's network, immunization services furnished by that provider would not necessarily be subject to coverage or exempt from cost-sharing requirements.

Ensuring that health plans include immunization providers in their networks has been identified as a critical issue by a diverse group of stakeholders. In addition to the individual efforts of our respective organizations, we have worked together to advance the aforementioned goals of expanding access to immunizations for the entire population and achieving the Healthy People 2020 goals for immunization through the National Adult and Influenza Immunization Summit (NAIIS). NAIIS is a public-private partnership compromised of more than 140 organizational stakeholders, including vaccine manufacturers, professional medical societies, public health organizations including state and local health departments, federal agencies, pharmacists, health insurers, and hospitals, among others. NAIIS has identified the issue of network adequacy for immunization providers as critical to vaccine access.

Notably, immunization services have a unique set of providers. In addition to traditional immunizers, such as pediatricians and other primary care providers, "complementary immunizers" like pharmacists, public health department clinics, and school-based clinicians provide many vaccines.

These complementary immunizers are particularly important for the hard-to-reach adult, and some, adolescent populations. Indeed, adults have demonstrated a preference to be vaccinated outside of their medical home, where and when it is convenient for them, and the system has evolved to support that access. For instance, more than 230,000 pharmacists have been trained to administer vaccines in the United States,[6] and nearly all Americans (94%) live within five miles of a community pharmacy.[7] During the 2011-2012 influenza season, nearly 20 percent of adult influenza vaccines were administered in retail pharmacies.[8] All 50 states allow pharmacists to administer pneumococcal and zoster vaccines and many adults seek these vaccines in the pharmacy setting.[9]

Meanwhile, many public health stakeholders have supported efforts underway at the CDC to include other complementary immunization sites, such as public health department and school-based clinics, in provider networks. The most significant such CDC initiative, known as the "Third Party Billing Project," works with state health departments, public health clinics, and health insurers to include public health department clinics in provider networks.[10] To date, 35 states and large cities are currently planning or implementing the Billing Project, which will allow them to directly bill insurers for immunization services

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[6] See Rothholz M. Opportunities for Collaboration to Advance Progress towards "The Immunization Neighborhood:" Recognition and Compensation of Pharmacists. Presentation. American Pharmacists Association. August 30, 2012.

[7] NCPDP Pharmacy File, ArcGIS Census Tract File, National Association of Chain Drug Stores Economics Department.

[8] CDC, March Flu Vaccination Coverage United States, 2011-12 Influenza Season (March 2012), available at: http://www.cdc.gov/flu/pdf/fluvaxview/national-flu-survey-mar2012.pdf.

[9] See American Pharmacists Association, Pharmacist Authority to Immunize, available at: http://www.pharmacist.com/sites/default/files/PharmacistIZAuthority.pdf

[10] CDC, Billing Project Success Stories, http://www.cdc.gov/vaccines/programs/billables-project/success-stories.html (last accessed Feb. 6, 2014).

provided to insured persons of all ages. Data from the Billing Project underscore the sheer volume of immunizations furnished by these complementary immunizers: in 2010 local health units billed private insurance for $1,964,267 in immunization-related costs in North Dakota alone.[11] Other states such as Arizona, California, Arkansas, Georgia and Montana have also experienced success with the Billing Project.[12]

In spite of these efforts, when a QHP does not include these complementary sites in its provider network, the ACA's intent of expanding access to immunizations is compromised. For instance, a QHP enrollee who seeks to be immunized at a public health clinic or pharmacy that has been excluded from a QHP's provider network would be denied first dollar coverage (or coverage at all) for that service. In turn, the patient may decide not to receive the vaccine due to cost and an immunization opportunity would be lost. Alternatively, a more affluent patient could elect to pay the bill, but none of these costs would count towards the patient's deductible, and the patient would understandably be upset and confused as to why they did not receive the benefits they were promised.[13]

In our experience, complementary immunizers are currently being excluded from provider networks across the country. For instance, school-based clinics in Carson City, Nevada have been excluded from the network of a major health insurer. Meanwhile two insurers will not contract with the School-Located Vaccine Clinic program operated by the health department in Pomperaug, Connecticut. And the Los Angeles Unified School District cannot bill insurers due to the perception that a vaccine given in a school will interfere with the medical home.

This need not be the case. Instead, CMS can and should monitor QHP compliance with the "immunization coverage standard," including as an integral part of the process, assessing these plans' network adequacy. Specifically, CMS should ensure that QHP beneficiaries have access to a robust network of immunizers, including "complementary immunizers," pursuant to the ACA's network adequacy and Essential Community Provider (ECP) requirements, as described in greater detail below. As acknowledged by the National Vaccine Advisory Committee (NVAC) in the updated Standards for Adult Immunization Practice, "there is an increased recognition of community vaccinators and pharmacists as integral to achieving higher adult vaccination rates."[14] Inclusion of these providers in the networks of QHPs will improve vaccination rates, thereby reducing overall medical care costs, morbidity, and mortality. Collaboration, coordination and communication among care providers can ensure reasonable and timely delivery of immunization services.

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[11] Sander M. Lessons Learned: Billing Insurance at Local Health Units in North Dakota (PowerPoint). March 30, 2011. North Dakota Department of Health. Available at: https://cdc.confex.com/cdc/nic2011/webprogram/Paper25418.html.

[12] Kilgus D. Billing Program Final Plans. February 2012. CDC. Available at: http://www.cdc.gov/vaccines/programs/billables-project/downloads/billing-final-plans-from-stkhldr-mtg-slides.pdf

[13] See Michelle Andrews, Consumers Expecting Free "Preventive Care" Sometimes Surprised by Charges (Jan. 21, 2014), available at: http://www.kaiserhealthnews.org/Stories/2014/January/21/Michelle-Andrews-Consumers-Expecting-Free-Preventive-Care.aspx.

[14] National Vaccine Advisory Committee. Standards for Adult Immunization Practice. Available at: http://www.hhs.gov/nvpo/nvac/meetings/pastmeetings/2013/adult_immunization_update-sept2013.pdf

II. In Implementing its New Network Adequacy Standard, CMS Should Also Focus on Those Provider Types Necessary to Ensure Patient Access to ACA-Covered Services, Including ACIP-Recommended Immunizations (Ch. 2, § 3)

Network adequacy generally refers to a health plan's ability to deliver the benefits promised by providing access to a sufficient number of in-network healthcare providers. The requirement to maintain a robust provider network is particularly critical with respect to the ACA's "immunization coverage standard," as the requirement to cover ACIP-recommended immunizations without cost-sharing applies only with respect to in-network providers. Thus, to ensure that the "immunization coverage standard" is not an empty promise, CMS must ensure that QHP networks include a broad range of immunization providers, including complementary immunizers, that are conveniently located throughout the plans' service areas.

We believe that CMS has taken steps in the right direction to ensure that QHPs offered through the FFM maintain robust provider networks. But there remains work to be done, particularly with respect to immunization providers.

To start, we would like to express our strong support for CMS's proposal to abandon its reliance on issuer accreditation status and state review processes as a proxy for plan compliance with the ACA's network adequacy requirements. We believe that these standards provided a useful transition for 2014, but that the time has come for CMS to establish new standards and review processes that ensure that QHPs offered through the FFM and Partnership Exchanges "maintain a network that is sufficient in number and types of providers . . . to assure that all services will be accessible without unreasonable delay."[15]

We also generally support CMS's proposed "reasonable access" standard, which we believe is broad enough to accommodate the fact that healthcare providers (and demand therefore) are not evenly distributed across the country, while helping to ensure that all QHPs maintain the robust provider networks required by the ACA. Moreover, we believe that CMS's proposal to focus on those areas that have "historically raised network adequacy concerns"—including primary care providers—will help to close historical gaps in access. That said, we are very concerned that the proposed standard fails to ensure that QHP beneficiaries can access the specific benefits to which they are entitled under the ACA, including ACIP-recommended immunizations. While the reasons for racial and socioeconomic disparities in adult immunizations are often multi-factorial and complex, one major contributing factor is access to vaccines. Accordingly, we urge CMS to modify its "areas of focus" such that CMS's network adequacy review also assesses plan networks for the inclusion of complementary immunizers (i.e., pharmacies, public health clinics, school-based clinics, and other community sites), which are necessary to ensure access to these critical preventive services.

III. CMS Should Refine the Essential Community Provider Standards by Requiring QHPs to Include in their Networks All Types of Complementary Immunization Providers (Ch. 2, § 3)

[15] 45 C.F.R. § 156.230.

Under the ACA, QHPs must include within their "health insurance plan networks those essential community providers, where available, that serve predominately low-income, medically underserved individuals."[16] This requirement is a critical aspect of mitigating the barriers these vulnerable patients have long faced with respect to access to care, and we support CMS's continuing and evolving efforts to implement this standard.

Indeed, relative to the approach employed in 2014, CMS has taken several steps to revise the ECP standard for 2015 in an effort to improve access to ECPs for some of the country's most vulnerable patients. For instance, CMS has proposed to eliminate the "minimum expectation" and will instead now require all QHPs to include at least 30 percent of the ECPs in their service area (an increase from 20 percent from last year). Moreover, all QHPs will be required to include at least one ECP from each provider type, subject to certain exceptions. We believe, however, that the standard should be further refined in two key regards.

First, we believe that CMS should add certain additional ECP provider types to the "Other ECP Providers" listed on page 24 of the Draft Letter. As you are aware, the ACA defines the term "Essential Community Provider" to refer to those individuals that "serve predominately low-income, medically-underserved individuals."[17] While the statute identifies certain specific provider types as part of the ECP definition—such as 340B covered entities—this list is not exhaustive.[18] We therefore urge CMS to take this opportunity to ensure that additional provider types that predominately serve vulnerable populations are also universally included in QHP provider networks, namely complementary immunizers.

Complementary immunizers—pharmacies, public health department clinics, school-based clinics, and other community providers—generally meet the definition of ECPs in that they often serve predominately low-income, medically under-served individuals. Take, for instance, community pharmacies, which provide patient access to important immunizations against vaccine-preventable diseases, including for individuals residing in medically underserved areas (MUAs). The geographic positioning and hours of operation of community pharmacies contribute to a plan meeting the "reasonable access" requirement. Indeed, one of the nationwide community pharmacy corporations, Walgreens, indicated that over one-third of their influenza vaccines administered last year were in pharmacies in MUAs; in states with the largest MUAs, they provided up to 77.1 percent of their influenza vaccines in these areas. Moreover, of all influenza vaccinations Walgreens delivered last season, 31 percent were during off-peak times (59 percent on weekends and 31 percent in the evenings), and approximately 31 percent of patients during off-peak times were age 65 or older, and 36 percent had underlying medical conditions. Notably, efforts to provide immunizations beyond those for influenza were complicated by lack of insurance coverage or recognition as in network providers. And there are many more providers with similar experiences.

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[16] ACA § 1311(c)(2)(C).

[17] Id.

[18] Id. (defining ECPs to include providers "that serve predominately low-income, medically-underserved individuals, such as health care providers defined in section 340B(a)(4) of the Public Health Service Act and providers described in section 1927(c)(1)(D)(i)(IV) of the Social Security Act . . . .") (emphasis added).

Given their critical role in ensuring access to immunization for low-income and medically-underserved individuals, we therefore urge CMS to add complementary immunizers to its list of "Other ECPs," as well as to its non-exhaustive list of ECPs available at http://cciio.cms.gov/programs/exchanges/qhp.html.

Second, we urge CMS to require QHPs to include all types of complementary immunizers in their provider networks—rather than "at least one"—to ensure beneficiaries have first dollar coverage of immunization services regardless of the delivery site.

IV. CMS Should Stipulate that all ACIP-Recommended Immunization Services Are Covered and Exempt from Cost-Sharing

While we believe it is essential for providers of immunization services to be included in QHP networks, and therefore urge CMS to take all available steps to ensure that this happens, we understand that universal inclusion of complementary immunizers may not be an attainable goal, at least initially. We therefore urge CMS to require QHPs to cover all ACIP-recommended immunizations without cost-sharing, regardless of whether they are furnished by in-network providers—either through the final 2015 Letter to Issuers, or via the regulations under development by the Agency. In doing so, we urge the Agency to adopt an approach similar to the standard implemented for emergency room services pursuant to section 2719A of the PHS Act.[19] Together with ensuring that immunization providers are included in QHP provider networks, adopting an across-the-board policy ensuring that all QHPs extend access to ACIP-recommended immunization services with no cost-sharing will ensure that beneficiaries have robust access to these services in accordance with section 2713 of the ACA.

V. Conclusion

We appreciate this opportunity to comment on the Draft Letter. We look forward to continuing to work with CMS and interested partners in designing standards for QHP certification to ensure that QHP beneficiaries have meaningful access to all ACIP-recommended immunizations with no cost-sharing. We believe this will not only help fulfill the ACA's promise of universal access to these important services, but will have major public health benefits as the result of such access. Please feel free to contact Kelly Cappio at (202) 292-4681 or kcappio@bio.org if you have any questions or if we can be of further assistance. Thank you for your attention to this important matter.

Respectfully submitted,

American Pharmacists Association
Association of State and Territorial Health Officials
Biotechnology Industry Organization
Immunization Action Coalition
Merck
National Association of County and City Health Officials

[19] 42 U.S.C. § 300gg-19a; 45 C.F.R. § 147.138(b).