Mr. John O'Brien
Director, Healthcare and Insurance
United States Office of Personnel Management
1900 E. Street, NW
Washington, DC 20415

March 7, 2014

Re: Multi-State Plan Program Call Letter – 2014-002

Dear Mr. O'Brien:

Thank you very much for this opportunity to submit the following comments on the "Multi-State Plan Program Call Letter" (the "Call Letter") issued by the Office of Personnel Management (OPM) on February 4, 2014.[1] We, the undersigned organizations, are committed to expanding access to immunizations for the entire population—including individuals enrolled in Multi-State Plans (MSPs) through the health insurance Marketplaces—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 MSPs 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 OPM's efforts to provide additional operational and technical details to issuers of MSPs through the draft Call Letter and other guidance, we still have concerns that the standards and review procedures described in the Call Letter may leave enrollees without access to critical immunization services, contrary to the intent of the ACA. In particular:

- There is a critical need for OPM to ensure MSP compliance with the ACA's "immunization coverage standard," as this requirement is inextricably intertwined with the law's requirements related to network adequacy;

[1] Office of Personnel Management, Multi-State Program Issuer Letter No. 2014-002 (Feb. 4, 2014), available at: http://www.opm.gov/media/4517978/2014-002_dms_.pdf.

- In reviewing the adequacy of MSP provider networks under 45 C.F.R. § 800.109 to ensure compliance with ACA § 1334(c)(1)(B),[2] in addition to those areas "where concerns have been raised about network adequacy," OPM should ensure that MSPs include in their networks those provider types that furnish benefits promised under the ACA—including ACIP-recommended immunizations;
- OPM should refine the applicable Essential Community Provider (ECP) standards by requiring MSPs 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 MSP's service area; and
- OPM 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 final Call Letter for 2015 or in the standard contract with MSP issuers for 2015.

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

I. OPM Should Ensure Compliance With the ACA's "Immunization Coverage Standard," as It Is Inextricably Intertwined with the Law's Network Adequacy Requirements

In reviewing MSP applications to participate in the health insurance Marketplaces, we strongly urge OPM to ensure MSP compliance with 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).[3] 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.[4] Therefore, to the extent 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

[2] As OPM is no doubt aware, this provision requires MSPs to comply with all requirements applicable to Qualified Health Plans (QHPs). This includes the network adequacy standards outlined in section 1311(c)(1)(B)-(C) of the ACA and its implementing regulations (45 C.F.R. §§ 156.230; 235).

[3] 42 U.S.C. §§ 300gg-13.

[4] 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.").

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,[5] and nearly all Americans (94%) live within five miles of a community pharmacy.[6] During the 2011-2012 influenza season, nearly 20 percent of adult influenza vaccines were administered in retail pharmacies.[7] All 50 states allow pharmacists to administer pneumococcal and zoster vaccines and many adults seek these vaccines in the pharmacy setting.[8]

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.[9] 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 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.[10] Other states such as Arizona, California, Arkansas, Georgia and Montana have also experienced success with the Billing Project.[11]

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[5] 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.

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

[7] 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.

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

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

[10] 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.

[11] 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

In spite of these efforts, when a MSP does not include these complementary sites in its provider network, the ACA's intent of expanding access to immunizations is compromised. For instance, a MSP enrollee who seeks to be immunized at a public health department clinic or pharmacy that has been excluded from a MSP'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.[12]

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, OPM can and should monitor MSP compliance with the "immunization coverage standard," including as an integral part of the process, assessing these plans' network adequacy under 45 C.F.R. § 800.109 to ensure compliance with ACA § 1334(c)(1)(B). Specifically, OPM should ensure that MSP 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."[13] Inclusion of these providers in the networks of MSPs will thus also 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.

II. In Implementing its New Network Adequacy Standard, OPM Should Also Focus on Those Provider Types Necessary to Ensure Patient Access to ACA-Covered Services, Including ACIP-Recommended Immunizations

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.

[12] 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.

[13] 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

Thus, to ensure that the "immunization coverage standard" is not an empty promise, OPM must ensure that MSP networks include a broad range of immunization providers—including complementary immunizers—that are conveniently located throughout the plans' service areas.

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

To start, we commend OPM for its recognition in the Call Letter that "MSP issuers must provide adequate access to high-quality in-network care wherever they offer coverage" and that "[c]onsumers must be able to receive care from providers with the appropriate expertise to treat them without unreasonable delay." We would also like to applaud OPM for requiring that MSP issuers "have in place a process to provide timely exceptions to ensure that consumers who need care from out-of-network providers (because of rare or complex medical conditions or lack of in-network providers in a geographic area) can receive it with reasonable cost-sharing, applying enrollee costs to the in-network out-of-pocket maximum, and protection from balance billing." We believe that this "timely exceptions" requirement will provide an important backstop to the generally applicable network adequacy requirements, so that beneficiaries are not penalized for the fact that a provider is omitted from their plan's network for reasons beyond their control. We believe, however, that this exceptions process should literally be the exception, not the rule. We therefore urge OPM to strengthen its underlying network adequacy requirements in two key regards to ensure that MSP plan networks are sufficiently robust.

First, we believe that OPM should reframe the network adequacy obligations articulated in the Call Letter as obligations, rather than expectations. Throughout the network adequacy section of the Call Letter, OPM outlines a number of critical mechanisms to ensure that MSPs include a broad array of providers within their networks, including that MSP issuers: (1) have sufficient numbers and types of providers in their networks to meet the needs of a diverse population; (2) monitor their networks continuously for quality and access; (3) make prompt adjustments to networks as needed; and (4) take certain steps to provide consistent and continuous coverage throughout the United States. We are concerned, however, that the Call Letter frames these mechanisms as OPM's "expectations," meaning that MSP issuers may be inclined to view them as voluntary. We therefore urge OPM to modify the Call Letter language to clarify that MSP issuers <u>must</u> comply with each of these requirements as a condition of entering into a contract with OPM under section 1334 of the ACA.

Second, while we applaud OPM for its plan to "pay special attention to areas where concerns have been raised about network adequacy," we believe that OPM should provide further clarity by compiling a non-exhaustive list of provider types that meet this criterion. For instance, OPM could start with the list of providers identified in the "Draft 2015 Letter to Issuers in Federally-facilitated Marketplaces" issued by the Centers for Medicare & Medicaid

Services (CMS),[14] which includes primary care providers. We are also very concerned that the proposed standard fails to ensure that MSP beneficiaries can access the specific benefits to which they are entitled under the ACA, including ACIP-recommended immunizations. Accordingly, we urge OPM to modify its areas of focus such that OPM's network adequacy review also assesses plan networks for the inclusion of complementary immunizers (i.e., pharmacies, public health department clinics, school-based clinics, and other community sites), which are necessary to ensure access to these critical preventive services.

III. OPM Should Refine the Essential Community Provider Standards by Requiring MSPs to Include in their Networks All Types of Complementary Immunization Providers

Under the ACA, all MSPs must include within their "health insurance plan networks those essential community providers, where available, that serve predominately low-income, medically underserved individuals."[15] 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 OPM's efforts to implement this standard. We believe, however, that OPM should issue additional guidance regarding ECPs, either in the Call Letter or in the standard contract with MSP issuers for 2015.

Specifically, we urge OPM to adopt a similar ECP standard to that employed by CMS in the agency's "Draft 2015 Letter to Issuers in Federally-facilitated Marketplaces."[16] Under this approach, CMS proposes to require all qualified health plans (QHPs) to include at least 30 percent of the ECPs in their service area, and to include at least one ECP from a list of provider types based on the non-exhaustive list of ECPs identified by the ACA. We would also urge that OPM, as well as CMS, add certain additional ECP provider types to that list, namely complementary immunizers.

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 OPM to take this opportunity to ensure that additional provider types that predominately serve low-income and medically-underserved populations are also universally included in MSP provider networks.

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[14] 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.

[15] ACA §§ 1311(c)(1)(C); 1334(c)(1)(B). See also 45 C.F.R. 800.109(a)(3) (citing 45 C.F.R. § 156.235).

[16] 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.

[17] ACA § 1311(c)(1)(C).

[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).

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.

Given their critical role in ensuring access to immunizations for low-income and medically-underserved individuals, we therefore urge OPM to identify all complementary immunizers as ECPs in the final Call Letter or other guidance.

IV. OPM 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 MSP networks, and therefore urge OPM 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 OPM to require MSPs to cover all ACIP-recommended immunizations without cost-sharing, regardless of whether they are furnished by in-network providers—either through the Call Letter, or via the standard contract with MSP issuers for 2015. In doing so, we urge OPM 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 MSP provider networks, adopting an across-the-board policy ensuring that all MSPs 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 Public Health Service Act.

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

V. Conclusion

We appreciate this opportunity to comment on the draft Call Letter. We look forward to continuing to work with OPM and interested partners in designing standards for MSPs to ensure that MSP 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

Vaccine Education Center at The Children's Hospital of Philadelphia