



November 15, 2013

BY ELECTRONIC DELIVERY

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral [CMS-1443-P]

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule regarding the Medicare Program and the prospective payment system (PPS) for federally qualified health center (FQHC) services.

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. BIO membership includes both current and future vaccine developers and manufacturers who have worked closely with the public health community to support policies that help ensure access to innovative and life-saving vaccines for all individuals.

The following discussion addresses two recommendations:

- BIO urges CMS to provide clarification to FQHCs regarding coverage of all vaccines recommended for Medicare beneficiaries, especially as it relates to vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) and covered and reimbursed under Medicare Part D.
- BIO also recommends that CMS apply a consistent approach to reimbursement for vaccines covered under Part B so as to ensure broad access for Medicare beneficiaries.

Comments

I. Clarification regarding coverage of all ACIP-recommended vaccines

In Section I.A.4, "Medicare's Current Reasonable Cost-Based Reimbursement Methodology", CMS describes vaccine coverage in FQHCs for influenza, pneumococcal, and hepatitis B vaccines:

"The administration and payment of influenza and pneumococcal vaccines is not included in the AIR (all-inclusive rate). They are paid at 100 percent of reasonable costs through the cost report. The cost and administration of hepatitis B vaccine (HBV) is covered under the FQHC's AIR."

The passage above from the proposed rule does not describe vaccine coverage or access for Medicare beneficiaries as it relates to ACIP-recommended vaccines covered under the Part D benefit, such as tetanus, diphtheria, and acellular pertussis (Tdap) vaccines and herpes zoster vaccines, nor, as far as we are aware, do other CMS publications or resources for FQHCs specifically address access to Part D vaccines for Medicare beneficiaries in FQHCs.

BIO member companies and their field staff interact frequently with FQHCs to discuss vaccines recommended for adults. Numerous FQHCs have expressed confusion regarding coverage of Part D vaccines in FQHCs, and that they are hesitant to recommend and administer vaccines other than influenza, pneumococcal and hepatitis B, because they are uncertain as to whether the cost of the vaccine(s) administered will be included in the encounter-based payment, or should be administered through a different process.

In Section I.A.4, CMS goes on to note that "FQHCs are accustomed to billing for a single visit, as they are currently paid through an AIR that is based on an FQHC's average cost per visit...We believe an encounter-based payment rate for the FQHC PPS would provide appropriate payment while remaining administratively simple." Since the encounter-based form of payment is the typical process for FQHCs, it seems that many FQHCs appear to think that Part D vaccines would need to be provided through an encounter-based payment approach, rather than accessed through use of Part D vaccine access mechanisms such as in-network pharmacies or electronic claims adjudication networks.

BIO proposes that CMS specifically address coverage policies and appropriate access for Medicare beneficiaries receiving Part D vaccines in FQHCs in the final rule, in order to clarify that Part D vaccines are not part of the encounter-based payment, and should instead be reimbursed separately by Part D plans.

II. Consistency in reimbursement for vaccines covered under Part B

CMS proposes to exclude the administration and payment of influenza and pneumococcal vaccines from the AIR. Instead, they would be paid at 100 percent of reasonable costs through the cost report. However, the cost and administration of hepatitis B vaccine would still be covered under the FQHC's AIR.

BIO believes that CMS should consider paying for hepatitis B vaccine cost and administration at 100 percent of reasonable costs, as proposed for influenza and pneumococcal vaccines. This approach would provide consistency in reimbursement procedures for Part B-covered vaccines and ensure equal and broad access to all Part B vaccines.

Conclusion

BIO greatly appreciates the opportunity to comment on the proposed rule regarding the Medicare PPS for FQHC services, and we look forward to continuing to work with CMS to ensure that Medicare beneficiaries have broad access to vaccines. Please contact us if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Sincerely,

Handwritten signature of Kelly Cappio in black ink.

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