House and Senate Democrats Introduce CHIP Funding Legislation

On February 12, Democratic health care leaders in the House and Senate introduced legislation to extend funding for the Children’s Health Insurance Program (CHIP). The CHIP program finances health coverage for over 8 million children and families via both federal and state funding and has a strong bipartisan history. It is authorized through 2019, but federal funding is due to expire at the end of September 2015 without congressional action.

To extend funding through 2019 and make other program improvements, House Energy and Commerce Democrats introduced the CHIP Extension and Improvement Act, H.R. 919. Led by Ranking Member Frank Pallone (D-NJ) and Health Subcommittee Ranking Member Gene Green (D-TX), the legislation has a total of 22 cosponsors—including every Democratic member of the Energy and Commerce Committee.

Across the Capitol, Senator Sherrod Brown (D-OH) introduced the Protecting and Retaining Our Children’s Health Insurance Program Act (PRO-CHIP) Act, S. 522. The Senate bill also extends CHIP funding through 2019, but also would extend other program components, such as quality measure programs and outreach/enrollment grants. Every member of the Senate Democratic Caucus—including the two Independents who caucus with Democrats—is a cosponsor of S. 522.

While the CHIP program has enjoyed strong bipartisan support, the introduction of H.R. 919 and S. 522 were Democratic efforts that do not include Republican support. It remains unclear exactly when and how Republicans—who control both the House and Senate—will act on a CHIP funding extension.

Press releases from the sponsors of H.R. 919 and S. 522 can be found here and here.

CMS Announces Oncology Care Model

Also on February 12, the Centers for Medicare and Medicaid Services announced a new initiative to encourage better oncology care; CMS issued a Request for Information on advanced primary care model initiatives; and The FDA reopened the comment period on its generic drug labeling proposal and announced it will hold a public hearing on the issue.
CMS announced a new multi-payer payment and care delivery model to support better coordination for oncology care. The Oncology Care Model (OCM) is part of the agency’s ongoing development of new payment and service delivery models that will improve quality and reduce the cost of specialty care.

Specifically, the OCM is a five-year, multi-payer model that will begin in the Spring of 2016. Practices will enter into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy treatment and the spectrum of care provided to a patient during a six-month episode following the start of chemotherapy. Physician practices furnishing chemotherapy treatment may participate in the care model.

Overall, the OCM will seek to provide better quality care and highly coordinated oncology care at a lower cost. Upon announcing the new care model, CMS’ Chief Medical Officer and Deputy Administrator for Innovation and Quality, Patrick Conway, M.D., stated: “We aim to provide Medicare beneficiaries struggling with cancer with high-quality care around the clock and to reward doctors for the value, not volume, of care they provide. Improving the way we pay providers and deliver care to patients will result in healthier people.”

Payers and practices who are interested in participating in the OCM must first submit a non-binding letter of intent (LOI). LOIs for payers are due on March 19, and LOIs for practices are due on April 23. Those who submit timely and complete LOIs will then be eligible to submit an application—due on June 18.

A press release from CMS can be found here and a fact sheet on the initiative can be found here. Specific eligibility and application instructions—including the LOI links—can be found here.

CMS Issues RFI on Advanced Primary Care Initiatives

On February 13, the Center for Medicare and Medicaid Innovation (CMMI)—part of CMS—issued a Request for Information (RFI) seeking input on initiatives to test innovations in advanced primary care.

According to the agency, advanced primary care is based on principles of the Patient Centered Medical Home and builds on the care delivery models employed in other CMS model tests, in order to further improve the delivery of patient-centered care and population health.

Input from the RFI will be used to design the next generation of advanced primary care models. Specifically, CMMI is seeking input on mechanisms and efforts that will encourage more comprehensiveness in primary care delivery, improve the care of complex patients, facilitate robust connections to the medical neighborhood and community-based services, and move reimbursement from encounter-based towards value-driven,
population-based care.

The advanced primary care RFI follows the agency's late-January release of the first findings from two multi-payer initiatives testing advanced primary care—the Comprehensive Primary Care (CPC) Initiative and the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration. These two initiatives found decreased hospital admissions, decreased emergency department visits and the potential for steady improvements in participating practices' advanced primary care capabilities.

Stakeholders wishing to respond to the advanced primary care RFI must do so by March 16 via the RFI link found here. Questions about the submission process should be directed to APC@cms.hhs.gov. Additional information on CMMI's advanced primary care initiatives can be found here.

FDA Reopens Comment Period on Generic Drug Labeling and Announces Public Meeting on the Issue

On February 17, the Food and Drug Administration (FDA) announced that it would reopen the comment period for its controversial proposed rule for generic drug labeling. First proposed in 2013, the rule would require generic drug makers to modify their labels independently of their brand-name counterparts. The FDA originally planned to issue a final rule in December 2014, but delayed the release in light of the contentious nature of the proposal.

The proposed rule was met with strong opposition from the generic drug industry, who believes that unilaterally requiring generic drug makers to change their labels would result in differing labels between the generic and brand name drugs, increase liability for generic drug companies, and increase generic drug prices. In its February 17 announcement, the FDA noted that it had received numerous comments from a diverse group of stakeholders, including proposed alternative approaches to communicating newly-acquired safety information in a multi-source environment.

In addition to the reopened comment period, the FDA also announced that it will hold a public meeting on the issue, in response to industry requests for an opportunity to present alternative approaches. "In view of these requests and to promote transparency, FDA will hold a public meeting at which any stakeholders may present or comment on the proposed rule or any alternative proposals intended to improve communication of important newly acquired drug safety information to health care professionals and the public," the FDA said in a statement.

The public meeting will be held on March 27 from 8:00 a.m. to 5:00 p.m. at the FDA's White Oak Campus in Silver Spring, Maryland, and registration to attend the meeting must be received by March 20.
The FDA announcement on both the comment period and the public meeting was published in the Federal Register on February 18 and can be found here. It contains detailed information on the meeting—including location, registration and requests for oral presentations—as well as instructions on submitting written comments, which are due by April 27.

**CONTACT US**

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