Trump administration releases plan to lower drug prices

On May 11, the Trump administration released its much-anticipated plan to lower drug prices and federal drug spending. Titled "American Patients First: The Trump Administration's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," the plan builds on proposals released by the administration earlier in 2018, attempting to lay out a multifaceted approach to tackle high drug costs.

The blueprint includes a significant number of proposals including:

- Accelerated approvals and increased competition in generic drug space at FDA.
- Modify Medicaid drug rebate rules and test other reforms at the state level.
- Numerous possible changes in Medicare Parts B and D, including restarting the Competitive Acquisition Program and moving some Part B drugs to Part D.
- Changes to 340B drug discount program.
- Examination of the role of pharmacy benefit managers (PBMs).
- Review of foreign drug pricing policies and impact on U.S. drug pricing.
- While a number of proposals were included in the plan, significant detail on how the administration plans to implement the proposed changes is lacking. It is likely that many of the suggestions would require regulatory changes or new legislative action.

The AMA is reviewing the blueprint (PDF) and the accompanying request for information and is planning to submit detailed comments to the administration. Comments are due July 16.

House and Senate committees act on legislation to address opioid abuse

Multiple committees in the House and Senate approved legislation during the weeks of May 14 and May 21 to address opioid abuse.

In the House, on May 16, the Committee on Ways and Means considered and approved several bipartisan bills to address the opioid epidemic in the context of the Medicare program. In a letter to the committee (PDF), the AMA expressed support for several of the provisions in these bills while
also making recommendations to improve other provisions.

The Energy and Commerce Committee held its second markup on May 17 to consider an additional 32 bills to address the opioid epidemic. The AMA submitted a letter for the record (PDF) highlighting our position on many of the bills. In total, the Energy and Commerce Committee approved 57 bills—53 by voice vote—during its two markups. The House is expected to vote on legislation that was considered in various committees during the week of June 11.

In the Senate, the Committee on Commerce, Science and Transportation and the Committee on the Judiciary each approved multiple measures on a bipartisan basis on May 22 and 24, respectively, to address the opioid abuse crisis. Additionally, on May 23, the Committee on Finance announced the introduction of 22 bipartisan bills by members of the Committee to address the opioid epidemic.

The Finance Committee is expected to markup these measures during June. The AMA is continuing to engage in the process in both the House and Senate to ensure that effective policies are adopted to address this national crisis.

**AMA comments on FDA draft guidance for compounding from bulk substances**

On May 25, the AMA submitted comments on the U.S. Food and Drug Administration’s (FDA) draft guidance (PDF), "Evaluation of Bulk Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act."

The draft guidance, which was released earlier in 2018, lays out the FDA’s plan to consider when an outsourcing facility may appropriately compound from bulk substances as opposed to an FDA-approved product. The Drug Quality and Security Act permitted compounding from bulk substances in cases where there is a "clinical need" for the product.

The draft guidance proposed that the FDA would make determinations of clinical need and would also determine if FDA-approved products were "medically unsuitable" for certain patients. In its comments, AMA noted concern with the FDA’s proposal to make determinations of clinical need and medical suitability of certain drug products without designating a role for physicians and their specialty societies in those determinations.

The AMA strongly urged the FDA to work with physicians and specialty societies to develop a process for making those determinations in collaboration.
On May 23, the Senate passed S. 2372, the "Department of Veterans Affairs Maintaining Internal Systems and Strengthening Integrated Outside Networks (VA MISSION) Act," by a 92–5 vote. It had previously passed the House on May 16 by a vote of 347–70. The president is expected to sign the measure into law shortly.

This bill streamlines the VA's various community care programs into a single, cohesive program, ensuring that veterans have continuity of care external to the VA's medical network. It also invests in the modernization of VA medical care facilities, expands veterans’ access to clinically validated telehealth services within the VA, and authorizes $5.2 billion in urgently needed funds to prevent interruption of veterans using the Choice Program.

In addition, the bill will continue to fund vital programs to recruit and retain health care professionals to provide quality care for veterans. The bill establishes a loan repayment program for medical residents who are training in specialties deemed by the VA to be experiencing a shortage. It also will fund scholarships to medical students in exchange for service to the VA following residency training. Two-sided ACO risk models result in higher spending A new report from the Center for Healthcare Quality and Payment Reform's CEO Harold Miller deconstructs performance data on Medicare Shared Savings Program accountable care organizations (ACOs). The report shows that, on average, ACOs in two-sided risk models have higher per-beneficiary spending than those in upside-only models.

The report suggests that the methodologies used to set ACO benchmarks, adjust for patient risk factors, and measure quality all tend to distort assessments of ACO performance. Miller recommends that Medicare replace the shared savings approach that it has been using to date with patient-centered alternative payment models that provide the resources physicians need to successfully address their patients' health care needs while holding them accountable for those aspects of spending and quality they can control.

AMA commends outreach on direct provider contracting

In a letter to the Center for Medicare and Medicaid Innovation (CMMI), the AMA offered detailed feedback on 22 questions posed by the CMMI in a request for information on its plans for a Direct Provider Contracting alternative payment model.
The AMA has long supported private contracts between patients and their physicians and views the Direct Provider Contracting model as an innovative approach with the potential to promote high levels of patient engagement and improve patient health outcomes. The comment letter (PDF) urged the CMMI to adopt an array of Direct Provider Contracting models including primary care, specialty and multispecialty pilots, and to use the Direct Provider Contracting model as a means of testing the 10 models that have been recommended by the Physician-focused Payment Model Advisory Committee.

The AMA also recommended that the CMMI employ the new model as a means to reduce physician regulatory burdens due to prior authorization requirements and ensure that the model does not impose unnecessary new administrative burdens.

In addition, the AMA called on the CMMI to support practices’ efforts to improve patient engagement by educating them about how best to utilize their services, which may include more timely appointment scheduling, after-hours and between visit phone call or email consultations, improved communication and coordination with other professionals and providers such as emergency departments, and services like remote patient monitoring and home visits.

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