May 17, 2018: Advocacy spotlight on Trump Administration releases drug pricing blueprint

Trump Administration releases drug pricing blueprint

On May 11, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint) was issued along with a request for information. The President framed the Blueprint as advancing four goals:

- Reducing list prices.
- Improving government's ability to negotiate better prices.
- Encouraging competition through rapid entry to market of generics and biosimilars.
- Lowering patient out-of-pocket expenses.

The Blueprint proposes a broad number of changes to prescription drug programs in several federal health care programs (Medicare, Medicaid, and other safety net programs) as well as Food and Drug Administration (FDA) policies that should impact commercial and federal health care program access to affordable prescription drugs.

While some of these proposals can be undertaken through immediate regulatory or subregulatory actions, others are still on the drawing boards at the U.S. Department of Health and Human Services and some will require congressional action to implement. Although the Blueprint proposes a select number of programmatic and design changes, there are a large number of questions for which the Administration is seeking feedback.

Based on a preliminary review, it appears that overall there will be increased access to lower-cost alternative generics. However, careful consideration by the AMA and Federation members will be needed on a number of proposed changes to the Medicare Part D prescription Drug Benefit program as well as the Part B drug reimbursement methodology.

One concern is that the proposed changes may limit patient access to medically necessary alternative brand or specialty treatments and result in additional administrative burdens on physicians and patients. Also of concern is the proposal to eliminate the requirement that Part D plans include a minimum of two drugs proven to be effective in each therapeutic category or pharmacologic class, if available.

The AMA will be preparing comments to the various proposals, but does applaud overall efforts to increase competition through a number of FDA proposals as well as proposed bans on gag clauses and ensuring a substantial portion of rebates are received by Medicare beneficiaries at the point-of-sale.

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