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# CMS to Let Medicare Advantage Plans Use Step Therapy with Care Coordination for Certain Part B Medications

Guidance, which starts January 2019, allows MA plans to require step therapy when two products are covered by Part B

The Centers for Medicare and Medicaid Services (CMS) issued an Aug. 7 [memorandum](#) that rescinds a September 2012 rule prohibiting Medicare Advantage (MA) plans from using step therapy for new starts to Part B-covered products. The new guidance memorandum, which kicks in January 2019, recognizes the use of utilization management in conjunction with patient care coordination to help lower medications, while also maintaining access to covered services and medications. AMCP has supported utilization management for Medicare Part B, including in July 2018 [comments](#) to the Department of Health and Human Services in response to its Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.

MA plans must still follow applicable national and local coverage determinations but may implement step therapy when an applicable coverage determination is silent. The guidance allows MA plans to require step therapy when 2 products are covered by Part B. MA plans may apply step therapy to require use of a Part B product before a Part D covered product as long as the coverage requirements for Part D coverage are documented, including prior authorization criteria submitted to CMS as outlined in the memorandum. Beneficiaries must be notified of the step therapy provisions during the plan's Annual Notice of Change and in Evidence of Coverage documents. Furthermore, plans must ensure that Medicare Part D covered products do not result in greater costs to beneficiaries and that coverage determination timeframes are followed.

CMS encourages plans to use care coordination, including beneficiary participation in conjunction with step therapy. AMCP is pleased that CMS defines care coordination as activities that are in the purview of pharmacists, physicians and nurses in health plans, including interaction medication review and consultations; providing educational materials and information; and implementing adherence strategies.

According to CMS, beneficiary participation may also mean incentive rewards. Rewards given to beneficiaries may not be in the form of cash or rebates but may be offered in the form of a gift card or "other items of value" that are

compliant with regulations governing Medicare Advantage and Chapter 4 of the Medicare Managed Care Manual. CMS interprets reasonable and appropriate incentives and rewards to be equivalent to more than half of the amount saved on average per participant by a more “efficient use of health care resources, promotion of improved health or prevention of injuries.”

Using step therapy or other utilization management may not be used to deny coverage of medically necessary services or eliminate access to a Part B covered benefit. MA plans must report the per member value of the savings in the annual Part C reporting requirements.

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## Capitol Hill Update

### Status of Relevant Legislation

The House is on recess and is set to return on Sept. 4th, while the Senate is scheduled to return today (Aug. 15th) from a two-week recess. Health care legislation awaiting Senate action includes the opioid-related bill (H.R. 6), which passed the full House at the end of June. Other recent health care-related legislation includes:

**H.R. 6478 – the Biosimilar Competition Act of 2018:** The bill was introduced July 23rd by Reps. John Sarbanes (D-MD) and Bill Johnson (R-OH). Current law requires brand and generic manufacturers to file patent settlement agreements with the Federal Trade Commission (FTC) and the Department of Justice (DOJ). The intent of the filings is twofold: (1) to allow the agencies to take enforcement action on anticompetitive agreements and (2) to deter manufacturers from entering into anticompetitive settlements. The FTC uses this information to: (1) publish an annual tally of anticompetitive reverse payment settlements, and (2) sue in federal court to prevent anticompetitive settlements from going into effect. This notification requirement, however, does not extend to biologic and biosimilar manufacturers, since the statutory requirement predates enactment of the biosimilars pathway under the Biologics Price Competition Act (BPCIA) by seven years. The purpose of BPCIA is to apply the existing filing requirements to biologic and biosimilar products. AMCP joined 17 other [stakeholders in a letter](#) to sponsors supporting H.R. 6478, and promised to work with them to pass it. The stakeholders share the commitment to promote a biosimilars market that will help reduce prescription drug costs for patients, payers and taxpayers.

**S. 974 – Creating and Restoring Equal Access to Equivalent Samples Act (CREATES ACT):** As reported last month, the Senate Judiciary Committee voted in favor of the S. 974 by a vote of 15-6. The bill is now on the Senate Legislative Calendar awaiting a vote by the full Senate. AMCP sent a [letter](#) in support of the legislation to each member of the Senate, and will call for AMCP grassroots advocacy in advance of a scheduled Floor vote.

## State Legislative Action

### Advocacy Tip

Be on the lookout for opportunities to voice your support or educate others on the benefits that managed care has to offer! Some legislators will sponsor town halls or call sessions with their constituents. These are also great opportunities to show you can be a resource outside of a traditional office visit, call or email. Follow your legislators on social media and/or sign up for their mailing lists.

## Status of Regular 2018 Sessions

The majority of states have already adjourned their regular sessions. However, Massachusetts, Illinois, Ohio, Pennsylvania, New York, New Jersey, Michigan, Wisconsin and the District of Columbia will continue to meet throughout the year. Meanwhile, California is set to adjourn by Aug. 31st, as are special sessions underway in Virginia and Maine.

**California Action on Electronic Prescribing (E-Rx) (Assembly Bill 2789):** AMCP is calling on members in California to please [Take Action NOW](#) in support of [AB 2789](#)! Let your state senator know that E-Rx is a useful tool that improves patient drug therapy, enhances the collection and analysis of patient data, increases operational efficiencies and optimizes health care outcomes and will decrease abuse and diversion of prescriptions for controlled substances. AMCP sent a [letter](#) to California's State Senate leadership in support of AB 2789, but they need to hear from you, AMCP members! This measure has already been passed by the Assembly and now is ready for a vote in the Senate. It is also supported by the California Pharmacists Association.

**NOTE:** *As this is a State Level Action Alert, only those members with California addresses will be able to send a letter on this legislation.*

## AMCP Activity

### AMCP Needs more Volunteers for the State Advocacy Coordinator Program

AMCP is looking for members in several states to volunteer as State Advocacy Coordinators (S.A.C.). These volunteers serve as the Academy's go-to members in each state, and are called upon to inform legislators, stakeholders and other AMCP members on advocacy efforts at both the state and federal levels. States can have more than one S.A.C., so if you are interested, but there is already an S.A.C. listed for your state, please contact us. Currently, 27 states and the District of Columbia need a S.A.C. If you would like more information on becoming a S.A.C, please [click here](#) to see the role of a S.A.C., which states are available, and to access the application form.

### AMCP Hosts Partnership Forum to Address High-Investment Medications

AMCP last month gathered more than 30 experts representing health plans, integrated delivery systems, pharmacy benefit managers, employers, national professional associations, the federal government, and biopharmaceutical companies to discuss new payment models needed to address emerging high-investment medications. Participants at the July 24-25 Partnership Forum in Baltimore agreed that the current infrastructure for providing compensation is not designed to meet the needs of high-investment medications, and a shift in the health care financing paradigm is needed to accommodate new breakthrough treatments. Participants observed that a "one-size-fits-all" approach cannot address all situations. Participants identified key roles for AMCP to advance innovative payment models, including acting as a convener of various stakeholders, conducting research and developing coalitions, acting as a repository of information, promoting education and awareness, and stimulating advocacy to address regulatory barriers. Read the July 30 [press release](#) describing the forum. Full proceedings from the

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Forum will be published in AMCP's *Journal of Managed Care & Specialty Pharmacy* in the coming months.

**Academy of Managed Care Pharmacy**

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