REPORT 3 OF THE COUNCIL ON MEDICAL SERVICE (November 2020)
Medicare Prescription Drug and Vaccine Coverage and Payment
(Resolution 203-A-19)
(Reference Committee A)

EXECUTIVE SUMMARY

At the 2019 Annual Meeting, the House of Delegates referred Resolution 203, "Medicare Part B and Part D Drug Price Negotiation," which was sponsored by the California Delegation. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2020 Annual Meeting. Resolution 203-A-19 asked:

> That our American Medical Association (AMA): (1) advocate for Medicare to cover all physician-recommended adult vaccines in both the Medicare Part D and the Medicare Part B programs; (2) make it a priority to advocate for a mandate on pharmaceutical manufacturers to negotiate drug prices with the Centers for Medicare & Medicaid Services (CMS) for Medicare Part D and Part B covered drugs; and (3) explore all options with the state and national specialty societies to ensure that physicians have access to reasonable drug prices for the acquisition of Medicare Part B physician-administered drugs and that Medicare reimburse physicians for their actual drug acquisition costs, plus appropriate fees for storage, handling, and administration of the medications, to ensure access to high-quality, cost-effective care in a physician's office.

Over the years, proposals aimed at lowering drug prices in Medicare Part B have also included provisions that would transition reimbursement for the cost of Part B drugs away from the current approach that is tied to average sales price (ASP) plus six percent (which has been reduced to 4.3 percent under the budget sequester). The Council recognizes that there has not yet been consensus among national medical specialty societies, and the house of medicine as a whole, concerning the preferred alternative(s) to using a rate tied to ASP to reimburse physicians and hospitals for the cost of Part B drugs. The Council believes, however, that the time is now for organized medicine to move forward with building consensus on which alternative methods would be preferred to reimburse physicians for the cost of Part B drugs. As a first step, our AMA should build upon past efforts and solicit input from national medical specialty societies and state medical associations for their recommendations to ensure adequate Part B drug reimbursement. Subsequently, the AMA should work with interested national medical specialty societies on alternative methods to reimburse physicians and hospitals for the cost of Part B drugs.

The Council recognizes that coverage and payment policies concerning vaccines under Medicare Parts B and D may be impacting the utilization rates of adult vaccines by Medicare patients, and raises financial risk for patients and physicians. While our AMA has ample, strong policy in this space, which are being recommended for reaffirmation, the Council believes that it is imperative for our AMA to continue to work with interested stakeholders to improve utilization rates of adult vaccines by Medicare beneficiaries. Underscoring the importance of lowering drug prices in Medicare Part D, the Council recommends the reaffirmation of policies that support the elimination of Medicare's prohibition on drug price negotiation; support CMS negotiating pharmaceutical pricing for all applicable medications covered by CMS, and outline safeguards to ensure that international drug price averages are used as a part of drug price negotiations in a way that upholds market-based principles and preserve patient access to necessary medications.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3, November 2020

Subject: Medicare Prescription Drug and Vaccine Coverage and Payment (Resolution 203-A-19)

Presented by: Lynda M. Young, MD, Chair

Referred to: Reference Committee A

At the 2019 Annual Meeting, the House of Delegates referred Resolution 203, "Medicare Part B and Part D Drug Price Negotiation," which was sponsored by the California Delegation. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2020 Annual Meeting. Resolution 203-A-19 asked:

> That our American Medical Association (AMA): (1) advocate for Medicare to cover all physician-recommended adult vaccines in both the Medicare Part D and the Medicare Part B programs; (2) make it a priority to advocate for a mandate on pharmaceutical manufacturers to negotiate drug prices with the Centers for Medicare & Medicaid Services (CMS) for Medicare Part D and Part B covered drugs; and (3) explore all options with the state and national specialty societies to ensure that physicians have access to reasonable drug prices for the acquisition of Medicare Part B physician-administered drugs and that Medicare reimburse physicians for their actual drug acquisition costs, plus appropriate fees for storage, handling, and administration of the medications, to ensure access to high-quality, cost-effective care in a physician's office.

This report provides background on how vaccines are covered and paid for under Medicare Parts B and D; outlines proposals that would allow for drug price negotiation under Medicare Part D; highlights approaches addressing drug prices and associated physician payment under Medicare Part B; and presents policy recommendations.

MEDICARE COVERAGE OF AND PAYMENT FOR VACCINES

Vaccines are covered in Medicare under Parts B and D. Medicare Part B covers the Hepatitis B vaccine for patients at high or intermediate risk; the influenza vaccine; the pneumococcal pneumonia vaccine; and vaccines directly related to treatment of an injury or direct exposure to a disease or condition (e.g., rabies, tetanus). In addition, should a vaccine become available for coronavirus (COVID-19), it will be covered under Medicare Part B, with no cost-sharing for Medicare beneficiaries for the vaccine itself or its administration.[1] At the time this report was written, no COVID-19 vaccine had been approved by the US Food & Drug Administration (FDA). Part D plans generally cover commercially available vaccines that Part B does not cover when they are reasonable and necessary to prevent illness, with required co-insurance rates and copayment amounts varying by plan. Vaccines covered under Part D could range from the shingles vaccine to vaccines for Hepatitis A.

In terms of physician payment for vaccines under Medicare Part B, physicians submit claims to their Medicare Administrative Contractor for the vaccine and its administration. When physicians agree to accept assignment for both the vaccine and its administration, which is common, patients

do not have to pay copayments or any contribution towards their Part B deductible for the seasonal influenza virus, pneumococcal, and Hepatitis B vaccines. Physicians who are in-network providers of their patient's Medicare Advantage plan submit claims to the plan for payment.

Under Medicare Part D, there are multiple pathways for vaccine payment and administration. Physicians may not be able to directly bill Part D plans for vaccines and their administration. In some cases, patients may need to pay their physicians up front for Part D vaccines, and then submit a claim to their Part D plan for reimbursement. If the physician's charge for the vaccine is greater than the plan's allowable charge, the patient would then be responsible for paying the difference. To limit patient out-of-pocket responsibilities, the physician can receive authorization, via a vaccine-specific notice requested by the physician or Part D plan enrollee. The vaccine-specific notice would provide the physician with instructions on how to receive a coverage authorization for a vaccine and how to submit an out-of-network claim, the plan's vaccine reimbursement rates, and any applicable cost-sharing responsibilities of the patient. In this situation, the physician would agree to accept payment received by the patient's Part D plan as payment in full, and the patient would pay the physician any cost-sharing amount required by their plan.

Alternatively, physicians can administer Part D vaccines and bill a patient's Part D plan through a web-assisted out-of-network billing system. To participate in such a system, the physician would enroll with a company with a portal through which they can electronically submit out-of-network claims for Part D vaccines they administer to their patient, the Part D plan enrollee. In this situation, the physician would also agree to accept payment received by the patient's Part D plan as payment in full, and the patient would pay the physician any cost-sharing amount required by the plan.

In addition, in some instances, prescriptions for Part D vaccines are transmitted to an in-network pharmacy of a patient's Part D plan. After the prescription is transmitted to an in-network pharmacy, there are two potential pathways for vaccine administration: the pharmacist administers the vaccine if permitted under state law; or the pharmacy fills the prescription and distributes it to the prescribing physician's office. In the latter scenario, the pharmacy bills the patient's Part D plan for the vaccine itself, with the pharmacy receiving any cost-sharing amount for the vaccine, and the physician receiving the cost-sharing associated with vaccine administration. Following the administration of the vaccine, the patient can submit the physician prescriber's charge for vaccine administration to their Part D plan for reimbursement.

Under Part D, vaccine administration costs are included as part of the negotiated price for a Part D vaccine. Part D plans can charge a single vaccine administration fee for all vaccines or multiple administration fees based on such factors as vaccine type and complexity of administration.

The complexity of Medicare Part D vaccine physician payment presents challenges and can add administrative burdens and costs to physician practices. Due to the variation in vaccine reimbursement rates of Part D plans, as well as the uncertainty of whether patients will be able to fulfill their out-of-pocket responsibilities, physicians assume risk as they determine how much Part D vaccine to stock, especially considering the need to stock vaccine products for other non-Medicare age groups served by their practices. The mechanisms of payment for vaccines under Part D exacerbate the issues faced by physician practices in having reimbursement not cover the true costs of providing immunizations, which extend beyond the price of the vaccine. These additional issues include the cost of vaccine storage equipment as well as administrative costs including monitoring temperature, ordering, maintaining supply and minimizing waste. The Council recognizes that smaller physician practices often encounter more challenges offering a full array of vaccine products to their patients, due to factors including vaccine acquisition costs and difficulties.

In addition, vaccine utilization rates among adults enrolled in Medicare have historically been, and continue to remain, low.[2] While the Affordable Care Act (ACA) drastically changed the cost-sharing requirements for vaccines under private health plan coverage and Medicaid, the law did not change cost-sharing requirements for vaccines covered under Medicare Part D. As a result, approximately four percent or less of enrollees of either stand-alone or Medicare Advantage prescription drug plans had access to ten vaccines without cost-sharing that are recommended by Advisory Committee on Immunization Practices either generally for adults ages 65 and older, or for adults with certain risk factors.[3] This level of access to these vaccines with no cost-sharing under Medicare Part D remained generally the same from 2015. Of note, no stand-alone Part D plan covered these vaccines with zero cost-sharing between 2015 and 2017.[4]

Relevant AMA Policy

Policy D-440.981 states that our AMA will: (1) continue to work with CMS and provide comment on the Medicare Program payment policy for vaccine services; (2) continue to pursue adequate reimbursement for vaccines and their administration from all public and private payers; (3) encourage health plans to recognize that physicians incur costs associated with the procurement, storage and administration of vaccines that may be beyond the average wholesale price of any one particular vaccine; and (4) advocate that a physician's office can bill Medicare for all vaccines administered to Medicare beneficiaries and that the patient shall only pay the applicable copay to prevent fragmentation of care.

Policy H-440.875 states that our AMA will aggressively petition CMS to include coverage and payment for any vaccinations administered to Medicare patients that are recommended by the Advisory Committee on Immunization Practices, the US Preventive Services Task Force (USPSTF), or based on prevailing preventive clinical health guidelines. Policy H-440.860 supports easing federally imposed immunization burdens by, for example: (i) Providing coverage for Medicare-eligible individuals for all vaccines, including new vaccines, under Medicare Part B; (ii) Creating web-based billing mechanisms for physicians to assess coverage of the patient in real time and handle the claim, eliminating out-of-pocket expenses for the patient; and (iii) Simplifying the reimbursement process to eliminate payment-related barriers to immunization. The policy also states that CMS should raise vaccine administration fees annually, synchronous with the increasing cost of providing vaccinations.

MEDICARE PART D DRUG PRICE NEGOTIATION

The "noninterference clause" in the Medicare Modernization Act of 2003 (MMA) states that the hSecretary of Health and Human Services (HHS) "may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." Instead, participating Part D plans compete with each other based on plan premiums, cost-sharing and other features, which provides an incentive to contain prescription drug spending. To contain spending, Part D plans not only establish formularies, implement utilization management measures and encourage beneficiaries to use generic and less-expensive brand-name drugs, but are required under the MMA to provide plan enrollees access to negotiated drug prices. These prices are achieved through direct negotiation with pharmaceutical companies to obtain rebates and other discounts, and with pharmacies to establish pharmacy reimbursement amounts.

In an effort to lower drug prices and patient out-of-pocket costs in Medicare Part D, multiple bills have been introduced in Congress to enable and/or require the Secretary of HHS to negotiate

covered Part D drug prices on behalf of Medicare beneficiaries. However, historically, the Congressional Budget Office (CBO), as well as CMS actuaries, have estimated that providing the Secretary of HHS broad negotiating authority by itself would not have any effect on negotiations taking place between Part D plans and drug manufacturers or the prices that are ultimately paid by Part D.[5,6]

In fact, CBO has previously acknowledged that, in order for the Secretary to have the ability to obtain significant discounts in negotiations with drug manufacturers, the Secretary would also need the "authority to establish a formulary, set prices administratively, or take other regulatory actions against firms failing to offer price reductions. In the absence of such authority, the Secretary's ability to issue credible threats or take other actions in an effort to obtain significant discounts would be limited."[7] CMS actuaries have concurred, stating "the inability to drive market share via the establishment of a formulary or development of a preferred tier significantly undermines the effectiveness of this negotiation. Manufacturers would have little to gain by offering rebates that are not linked to a preferred position of their products, and we assume that they will be unwilling to do so."[8]

Showing the impact of negotiating leverage, the December 10, 2019 CBO cost estimate "Budgetary Effects of HR 3, the Elijah E. Cummings Lower Drug Costs Now Act" stated that Title I of the legislation would reduce federal direct spending for Medicare by $448 billion over the 2020-2029 period.[9] In its October 11, 2019 estimate, CBO estimated that the largest savings would be the result of lower prices for existing drugs that are sold internationally, which would be impacted by the application of the "average international market price" outlined in the bill.[10] Title I of HR 3 would require the Secretary of HHS to directly negotiate with manufacturers to establish a maximum fair price for drugs selected for negotiation, which would be applied to Medicare, with flexibility for Medicare Advantage and Medicare Part D plans to use additional tools to negotiate even lower prices. An "average international market price" would be established to serve as an upper limit for the price reached in any negotiation, if practicable for the drug at hand, defined as no more than 120 percent of the drug's volume-weighted net average price in six countries – Australia, Canada, France, Germany, Japan and the United Kingdom.

Relevant AMA Policy

Policy D-330.954 states that our AMA: (1) will support federal legislation which gives the Secretary of HHS the authority to negotiate contracts with manufacturers of covered Part D drugs; (2) will work toward eliminating Medicare prohibition on drug price negotiation; and (3) will prioritize its support for CMS to negotiate pharmaceutical pricing for all applicable medications covered by CMS.

Addressing the use of international price indices and averages as part of the Secretary of HHS negotiating drug prices in Medicare Part D, Council on Medical Service Report 3-I-19 established Policy H-110.980, which outlines the following policy principles:

a. Any international drug price index or average should exclude countries that have single-payer health systems and use price controls;
b. Any international drug price index or average should not be used to determine or set a drug's price, or determine whether a drug's price is excessive, in isolation;
c. The use of any international drug price index or average should preserve patient access to necessary medications;
d. The use of any international drug price index or average should limit burdens on physician practices; and

e. Any data used to determine an international price index or average to guide prescription drug pricing should be updated regularly.

MEDICARE PART B DRUG PRICES AND PHYSICIAN PAYMENT

Medicare reimburses physicians and hospitals for the cost of Part B drugs at a rate tied to the average sales price (ASP) for all purchasers—including those that receive large discounts for prompt payment and high-volume purchases—plus a percentage of the ASP. Currently, the percentage add-on is six percent, which is then reduced to 4.3 percent under the budget sequester enacted in 2011. Over the years, there have been a number of calls for reductions in the ASP add-on, modifications in the calculation of the ASP, and inflation-related limits on Medicare increases in drug payments.

For example, in 2017, the Medicare Payment Advisory Commission (MedPAC) put forth proposals addressing the ASP payment system. Such proposals included reducing payment rates for new single-source Part B drugs that lack ASP data from 106 percent to 103 percent of wholesale acquisition costs; establishing an ASP inflation rebate; and developing a voluntary alternative, the Drug Value Program (DVP), to the ASP payment system for physicians and outpatient hospitals. Under the proposed DVP, providers would purchase all DVP products at the price negotiated by their selected DVP vendor; Medicare would pay providers the DVP-negotiated price and pay vendors an administrative fee; and Medicare payments under the DVP could not exceed 100 percent of ASP.[11]

Based on a June 2015 MedPAC report to Congress, in 2016, CMS, under the Obama Administration, put forward a proposed rule, *Medicare Program: Part B Drug Payment Model*, to implement a two-phase, multipronged nationwide model that would restructure the way Medicare reimburses physicians for Part B drugs. Under phase 1 of the model, CMS proposed to retain the current rates in some communities and set a reduced rate of ASP+2.5 percent in addition to a $16.80 flat fee in others. After the sequester is factored in, the add-on in the model areas would have been 0.86 percent of ASP plus $16.53. Under phase 2, five additional "value-based" drug payment strategies (test arms) were outlined to be on tap for implementation in specified localities in subsequent years. As a result, Medicare payment policy would have remained unchanged in approximately 25 percent of the country while multiple changes could have been applied to 75 percent of the country.[12] Due to strong opposition from the AMA and other stakeholders, the proposed rule was not implemented and eventually formally withdrawn.

In October of 2018, the Trump Administration released an Advance Notice of Proposed Rulemaking (ANPRM) entitled "International Pricing Index Model for Part B Drugs." The ANPRM did not represent a formal proposal, but rather outlined the Administration's current thinking and sought stakeholder input on a variety of topics and questions related to this new drug pricing model prior to entering formal rulemaking. Under the ANPRM, providers would select vendors from which to receive included drugs, but would not be responsible for buying and billing Medicare for the drug product. Instead, providers would continue to be entitled to bill a drug administration fee, and would also be entitled to receive a drug add-on fee. While the ANPRM was somewhat short on detail on exactly how this add-on fee would be calculated, it appears the add-on fee would be a flat fee that is based on six percent of the historical average sales price for the drug in question.[13]

In September 2020, an executive order "Lowering Drug Prices by Putting America First" was issued which called for testing of payment models to apply international price benchmarking to Part B and Part D prescription drugs and biological products. For Part B, the executive order

instructed the Secretary of HHS to implement rulemaking to test a payment model under which "Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price." The executive order defined the "most-favored-nation price" as "the lowest price, after adjusting for volume and differences in national gross domestic product, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organisation for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product." For Part D, the executive order instructed the Secretary of HHS to develop and implement rulemaking to test a payment model for high-cost Part D drugs, limiting payment to these drugs to the most-favored-nation price, to the extent feasible.[14] At the time that this report was written, no proposed and/or interim final rule had been issued to begin the implementation of the provisions of the executive order, which could also propose changes to Medicare Part B drug reimbursement.

Relevant AMA Advocacy and Policy

In its comments submitted in response to the ANPRM, the AMA stated that "reimbursement models based on an 'add-on' formula are intended to adequately reimburse physicians for the costs of acquisition, proper storage and handling, and other administrative costs associated with providing these treatment options for patients. Many drugs included in this model, such as biological products, are complicated drug products that require special attention to handling and storage to remain stable and viable for administration to patients. Drugs that require specific conditions for shipping, storage, and handling result in significantly higher administrative costs to physician practices than many small molecule-type drugs. Due to the special nature of these products, these costs are fixed, and will not decrease as the price of the drug goes down. Given these fixed administrative costs, the Council is very concerned that, should drug prices decrease as this model predicts, any add-on payment based on an ASP would ultimately decrease with the price of the drug and would no longer be sufficient to cover the administrative costs to the practice. If add-on reimbursement decreases enough that it is no longer sufficient to cover the expenses associated with providing these treatment options, it is likely that practices will no longer be able to offer these options for patients. The Council strongly urges CMS to consider the impact on the add-on as the IPI model over time could reduce this amount below actual clinician cost."

Policy D-330.960 supports efforts to seek legislation to ensure that Medicare payments for drugs fully cover the physician's acquisition, inventory and carrying cost and that Medicare payments for drug administration and related services are adequate to ensure continued patient access to outpatient infusion services. The policy also states that our AMA will continue strong advocacy efforts working with relevant national medical specialty societies to ensure adequate physician payment for Part B drugs and patient access to biologic and pharmacologic agents.

Addressing a Medicare Part B Competitive Acquisition Program (CAP), Policy H-110.983 states that it should provide supplemental payments to reimburse for costs associated with special handling and storage for Part B drugs; and that it must not reduce reimbursement for services related to provision/administration of Part B drugs, and reimbursement should be indexed to an appropriate health care inflation rate.

DISCUSSION

The prices and coverage of, and payment for, prescription drugs and vaccines under Medicare Parts B and D not only impact patients' ability to access the drugs and vaccines they need, but also impact the ability of physician practices to cover their costs associated with acquiring, storing and administering Part B drugs, and Part B and Part D vaccines. Over the years, proposals aimed at

lowering drug prices in Medicare Part B have also included provisions that would transition reimbursement for the cost of Part B drugs away from the current approach that is tied to ASP plus six percent (which has been reduced to 4.3 percent under the budget sequester). The Council recognizes that there has not yet been consensus among national medical specialty societies, and the house of medicine as a whole, concerning the preferred alternative(s) to using a rate tied to ASP to reimburse physicians and hospitals for the cost of Part B drugs. The Council believes, however, that the time is now for organized medicine to move forward with building consensus on which alternative methods would be preferred to reimburse physicians for the cost of Part B drugs. As a first step, our AMA should build upon past efforts and solicit input from national medical specialty societies and state medical associations for their recommendations to ensure adequate Part B drug reimbursement. The Council is hopeful that there will be a high level of participation among members of the Federation, in an effort to work collectively and collaboratively on this issue within the house of medicine. Subsequently, the AMA should work with interested national medical specialty societies on alternative methods to reimburse physicians and hospitals for the cost of Part B drugs.

The Council recognizes that coverage and payment policies concerning vaccines under Medicare Parts B and D may be impacting the utilization rates of adult vaccines by Medicare patients. There is a complicated web guiding coverage and payment for vaccines under Medicare Parts B and D, raising financial risk for patients and physicians. In addition, for some vaccines provided to Medicare beneficiaries, reimbursement to physician practices does not cover the true costs of providing immunizations, which extend beyond the price of the vaccine and also include the cost of vaccine storage equipment as well as administrative costs including monitoring temperature, ordering, maintaining supply and minimizing waste. While our AMA has ample, strong policy in this space, the Council believes that it is imperative for our AMA to continue to work with interested stakeholders to improve utilization rates of adult vaccines by Medicare beneficiaries. In addition, the Council recommends the reaffirmation of Policies D-440.981, H-440.875 and H-440.860, policies that contain strong and innovative approaches to improve the coverage and payment environment for vaccines under Medicare Parts B and D.

Recognizing the importance of lowering drug prices in Medicare Part D, the Council recommends reaffirmation of Policy D-330.954, which states that our AMA supports federal legislation which gives the Secretary of HHS the authority to negotiate contracts with manufacturers of covered Part D drugs; will work toward eliminating Medicare prohibition on drug price negotiation; and will prioritize its support for CMS to negotiate pharmaceutical pricing for all applicable medications covered by CMS. Finally, with the introduction of proposals that would use the average of a drug's price internationally to serve as an upper limit in drug price negotiations, the Council recommends the reaffirmation of Policy H-110.980, which outlines safeguards to ensure that international drug price averages are used as a part of drug price negotiations in a way that upholds market-based principles and preserves patient access to necessary medications.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 203-A-19, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) continue to solicit input from national medical specialty societies and state medical associations for their recommendations to ensure adequate Medicare Part B drug reimbursement. (Directive to Take Action)

2. That our AMA work with interested national medical specialty societies on alternative methods to reimburse physicians and hospitals for the cost of Part B drugs. (Directive to Take Action)

3. That our AMA continue working with interested stakeholders to improve the utilization rates of adult vaccines by individuals enrolled in Medicare. (Directive to Take Action)

4. That our AMA reaffirm Policy H-440.860, which supports easing federally imposed immunization burdens by, for example, covering all vaccines in Medicare under Part B and simplifying the reimbursement process to eliminate payment-related barriers to immunization; and urges the Centers for Medicare & Medicaid Services (CMS) to raise vaccine administration fees annually, synchronous with the increasing cost of providing vaccinations. (Reaffirm HOD Policy)

5. That our AMA reaffirm Policy D-440.981, which supports adequate reimbursement for vaccines and their administration from all public and private payers; encourages health plans to recognize that physicians incur costs associated with the procurement, storage and administration of vaccines that may be beyond the average wholesale price of any one particular vaccine; and advocates that a physician's office can bill Medicare for all vaccines administered to Medicare beneficiaries and that the patient shall only pay the applicable copay to prevent fragmentation of care. (Reaffirm HOD Policy)

6. That our AMA reaffirm Policy H-440.875, which states that our AMA will aggressively petition CMS to include coverage and payment for any vaccinations administered to Medicare patients that are recommended by the Advisory Committee on Immunization Practices, the US Preventive Services Task Force, or based on prevailing preventive clinical health guidelines. (Reaffirm HOD Policy)

7. That our AMA reaffirm Policy D-330.954, which supports the use of Medicare drug price negotiation. (Reaffirm HOD Policy)

8. That our AMA reaffirm Policy H-110.980, which outlines safeguards to ensure that international drug price averages are used as a part of drug price negotiations in a way that upholds market-based principles and preserve patient access to necessary medications. (Reaffirm HOD Policy)

Fiscal Note: Between $15,000 and $20,000.

REFERENCES

[1] Cubanski, J and Freed, M. FAQs on Medicare Coverage and Costs Related to COVID-19 Testing and Treatment. Kaiser Family Foundation. March 30, 2020. Available at: https://www.kff.org/medicare/issue-brief/faqs-on-medicare-coverage-and-costs-related-to-covid-19-testing-and-treatment/.
[2] US Government Accountability Office. Medicare: Many Factors, Including Administrative Challenges, Affect Access to Part D Vaccinations. December 2011. Available at: https://www.gao.gov/assets/590/587009.pdf.
[3] Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed (Boostrix®); zoster vaccine live (Zostavax®); varicella virus vaccine live (Varivax®); A/C/Y/W-135, meningococcal polysaccharide vaccine, groups A, C, Y and W-135 combined (Menomune®); hepatitis A vaccine (Havrix®); hepatitis A vaccine, inactivated (Vaqta®); hepatitis B vaccine recombinant (Engerix-B®); hepatitis B vaccine recombinant (Recombivax HB®); hepatitis A and hepatitis B recombinant (Twinrix®); and tetanus and diphtheria toxoids vaccine, adsorbed (Tenivac™).
[4] Wouters, A et al. Trends in Medicare Part D Benefit Design and Cost Sharing for Adult Vaccines, 2015–2017. Manatt Health Strategies. January 2018. Available at: https://www.manatt.com/Manatt/media/Documents/Articles/Medicare-Part-D-for-Adult-Vaccines-Issue-Brief.pdf.
[5] Congressional Budget Office. Letter to Senator Ron Wyden (D-OR) relating to options for allowing the Secretary of HHS to negotiate over the prices paid for drugs under that Medicare Part D. April 10, 2007. Available at: https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/drugpricenegotiation.pdf.
[6] Centers for Medicare & Medicaid Services. CMS Actuaries Conclude That H.R. 4 Would Have No Effect on Lowering Drug Prices. January 11, 2007. Available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2007-Press-releases-items/2007-01-11.html.
[7] CBO, *supra* note 5.
[8] CMS, *supra* note 6.
[9] Congressional Budget Office. Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. December 10, 2019. Available at: https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf.
[10] Congressional Budget Office. Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare. October 11, 2019. Available at: https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf.
[11] Medicare Payment Advisory Commission. Report to the Congress: Medicare and the Health Care Delivery System. June 2017. Available at: http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0.
[12] American Medical Association. Letter to Acting Administrator Slavitt in response to Medicare Program; Part B Drug Payment Model; CMS-1670-P. May 9, 2016. Available at: https://searchlf.ama-assn.org/letter/documentDownload?uri=/unstructured/binary/letter/LETTERS/medicare-program-part-b-letter-09may2016.pdf.
[13] Centers for Medicare & Medicaid Services. Medicare Program; International Pricing Index Model for Medicare Part B Drugs: Advance notice of proposed rulemaking. October 2018. Available at: https://www.govinfo.gov/content/pkg/FR-2018-10-30/pdf/2018-23688.pdf.
[14] The White House. Executive Order on Lowering Drug Prices by Putting America First. September 13, 2020. Available at: https://www.whitehouse.gov/presidential-actions/executive-order-lowering-drug-prices-putting-america-first-2/.