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POSITION PAPER

Policy Recommendations for Public Health Plans to Stem the Escalating Costs of Prescription Drugs: A Position Paper From the American College of Physicians

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The increasing price of prescription drugs is an ongoing concern for Medicare and Medicaid, particularly for patients with chronic health conditions who are using multiple medications and patients in these programs taking high-priced brand-name specialty drugs. Shifts in benefit design, including higher deductibles and a movement away from copayments to coinsurance, have increased patient out-of-pocket costs and put pressure on program budgets. In this paper, the American College of Physicians expands on its position paper from 2016 and offers additional recommendations to decrease out-of-pocket costs for patients, enhance the government's purchasing power, and address existing policies that add costs to the health care system.

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In 2016, the American College of Physicians (ACP) published "Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians," a series of recommendations to improve transparency, value, and competition for prescription drugs, with the goal of creating a sustainable and affordable prescription drug marketplace (1). The high prices and costs of prescription drugs in the United States continue to be a concern for patients, physicians, payers, policymakers, and government officials. Several recent proposals have looked at how to change the way prescription drugs are paid for through public health plans and how to decrease out-of-pocket costs for beneficiaries while mitigating potential incentives to keep drug prices high.

Background

The United States spends more on prescription drugs than other high-income countries, with average annual spending of $1443 per capita on pharmaceutical drugs and $1026 per capita on retail prescription drugs (2). Reports show that although use of prescription drugs in the United States is high, it is not an outlier compared with 9 other high-income nations (3). The primary differences between health care expenditures in the United States versus other high-income nations are pricing of medical goods and services and the lack of direct price controls or negotiating power by centralized government health care systems. For example, the cost of new hepatitis C drugs, initially priced at more than $80 000 for a course of treatment, accounted for 40% of the net growth in U.S. prescription drug spending in 2014 (4). The cost of the new generation of hepatitis C drugs has begun to drop off with intense public scrutiny and increased market competition; however, the pipeline for other high-cost specialty drugs is robust (5). These high costs are often passed on to patients and may result in patients delaying or forgoing care, which may lead to more serious health conditions.

The continued influx of baby boomers into Medicare from private health insurance plans is expected to affect trends in spending growth in the program for the next decade. The Medicare Part D prescription drug benefit is a voluntary program established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). As of 2018, more than 43 million of 60 million Medicare beneficiaries were enrolled in a Part D plan. Medicare expenditures account for a 29% share of all spending on retail prescription drugs, and in 2015, the Part D program spent $137.4 billion on drugs (6). Ten drugs accounted for 21% of Part D spending in 2015, including Harvoni (ledipasvir–sofosbuvir) for hepatitis C, Lantus (insulin glargine injection) for diabetes, Crestor (rosuvastatin calcium) for high cholesterol, Nexium (esomeprazole magnesium) for acid reflux, and Humira (adalimumab) for rheumatoid arthritis (7).

Medicaid has also seen recent increases in pharmaceutical spending. State Medicaid programs currently provide outpatient prescription drug coverage for all eligible beneficiaries. Medicaid spending on outpatient drugs increased by 25% (from $22.4 billion to $28 billion) between 2013 and 2014 and by another 13% (to $31.7 billion) between 2014 and 2015. This was primar-

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* This paper, written by Hilary Daniel, BS, and Sue S. Bornstein, MD, was developed for the Health and Public Policy Committee of the American College of Physicians. Individuals who served on the Health and Public Policy Committee at the time of the paper's approval were Sue S. Bornstein, MD (*Chair*); Jan K. Carney, MD (*Vice Chair*); Thomas G. Cooney, MD; Lee S. Engel, MD; Heather E. Gantzer, MD; Tracey L. Henry, MD; Joshua D. Lenchus, DO; Bridget M. McCandless, MD; Molly B. Southworth, MD; Fatima Syed, MD; Jacob Quinton, MD; Mary Anderson Wallace, MD; and Alexandria Valdrighi. Approved by the ACP Board of Regents on 3 November 2018.

ily attributable to the introduction of high-priced direct-acting antivirals, but the introduction of high-priced specialty drugs and the financial effect and long-term sustainability are of particular concern to policymakers (8). These types of unpredictable costs can drive rapid spending growth and need to be addressed as part of broader efforts to curb the increasing cost of health care in the United States.

METHODS

This policy paper was drafted by the Health and Public Policy Committee of the ACP, which is charged with addressing issues that affect the health care of the U.S. public and the practice of internal medicine and its subspecialties. The authors reviewed available studies, reports, and surveys about Medicare, Medicaid, and public health care programs from PubMed, Google Scholar, relevant news articles, policy documents, and Web sites. The literature review focused primarily on out-of-pocket spending by Medicare beneficiaries, the amount spent by Medicare on prescription drugs, Medicare Part D, Medicare Part B, Medicaid, and drug spending trends in the Medicaid program.

Recommendations were based on reviewed literature and input from the ACP's Board of Governors, Board of Regents, Council of Early Career Physicians, Council of Resident/Fellow Members, Council of Student Members, and Council of Subspecialty Societies. The policy paper and related recommendations were reviewed and approved by the ACP Board of Regents in November 2018. Financial support for the development of this position paper came exclusively from the ACP operating budget.

This executive summary provides a synopsis of the position paper. The full background and rationale are provided in the **Appendix** (available at Annals.org).

RECOMMENDATIONS

1. ACP supports modification to the Medicare Part D low-income subsidy (LIS) program cost-sharing and copayment structures to encourage the use of lower-cost generic or biosimilar drugs, such as eliminating cost sharing for generic drugs for LIS enrollees.

2. ACP supports annual out-of-pocket spending caps for Medicare Part D beneficiaries who reach the catastrophic phase of coverage.

3. ACP supports the adoption of Medicare Part D negotiation models that would drive down the price of prescription drugs for beneficiaries.

a. While ACP reaffirms its support for a full repeal of the noninterference clause, ACP also supports an interim approach, such as allowing the Secretary of Health and Human Services (HHS) to negotiate for a limited set of high-cost or sole-source drugs.

b. ACP supports a public Medicare Part D plan option that allows the Secretary of HHS to negotiate prices with drug makers. Any Medicare-operated public plan must meet the same requirements as private plans and be consistent with ACP's policy on formularies.

4. ACP supports efforts to minimize the financial impact on the federal government of prescription drug misclassification in the Medicaid Drug Rebate Program (MDRP). The Centers for Medicare & Medicaid Services should identify which legal authorities are necessary to ensure compliance with the MDRP and Congress should pass legislation to grant such authorities.

5. ACP supports further study of payment models in federal health care programs, including methods to align payment for prescription drugs administered in-office in a way that would reduce incentives to prescribe higher-priced drugs when lower-cost and similarly effective drugs are available.

SUMMARY

The United States spends more than other high-income countries on prescription drugs, and as the number of persons covered by Medicare increases and state Medicaid budgets are increasingly strained by high-cost brand-name drugs, action will be needed to ensure affordability for patients and government purchasers. Because the topic of prescription drug pricing continues to be of interest to patients, physicians, and government officials, ACP believes policymakers should act immediately to address current issues in the Medicare and Medicaid programs that add costs to the health care system, may inadvertently incentivize higher prices for prescription drugs, and increase out-of-pocket costs for consumers.

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Appendix: Background and Rationale

Medicare Part D Spending and Payment for Prescription Drugs

The Medicare Part D prescription drug program is a voluntary benefit that became available to Medicare beneficiaries with the passage of the MMA in 2003. In 2018, a standard Medicare Part D Plan included a deductible of up to $405; a copayment or coinsurance (typically for high-priced, specialty, or nonpreferred drugs) for prescriptions, with an initial coverage limit of up to $3750; and a coverage gap (also known as the "doughnut hole"), where beneficiaries pay a larger share of drug costs up to $5000. After reaching $5000 in out-of-pocket costs, beneficiaries enter the catastrophic coverage level (9). Low-income beneficiaries who are dually eligible for Medicare and Medicaid, qualified Medicare beneficiaries, specified low-income Medicare beneficiaries, qualified individuals, and persons receiving only Social Security automatically qualify for the low-income subsidy (LIS) program and are automatically enrolled in a prescription drug plan with premiums at or below the national average if they do not choose a plan of their own (9). Those in the LIS program pay nothing for prescription drugs once they reach the catastrophic phase, whereas those not in the program have a lower level of cost sharing but are at risk for high out-of-pocket costs (10). In 2015, 9% (3.6 million) of Medicare Part D beneficiaries had total drug spending above the catastrophic coverage threshold, and 72% of them (2.6 million) participated in the LIS program. After 2017, Medicare spending, including payments for prescription drugs, was projected to grow more rapidly than spending in private health plans.

Medicare also pays for a limited number of drugs through the Part B benefit, such as drugs used with durable medical equipment, injectable osteoporosis drugs, other injectable and infused drugs, and drugs used in the hospital outpatient setting (those used in patients under observation status in a hospital without being formally admitted or those used in same-day outpatient clinics). Payments for Part B drugs are calculated as the average sales price plus 6% (ASP+6%), a formula that was implemented in 2006 after passage of the MMA. As part of the 2012 budget sequester, the Centers for Medicare & Medicaid Services (CMS) was required to cut Part B payments by approximately 2%, making the current reimbursement rate ASP+4.3%. In 2015, Medicare Part B drugs, including those administered by physicians, suppliers, and hospital outpatient departments, accounted for $25.7 billion in Medicare expenditures, with physicians and suppliers accounting for two thirds ($17.0 billion) of Part B spending (11). Although Part B covers a range of drugs, including some lower-cost generics, the top 10 drugs that account for the largest share of Part B spending are more expensive and typically range from $1000 to $6000 per administration (12). Most of them are biologics with no biosimilar competition.

Medicaid Spending and Payment for Prescription Drugs

Medicaid payments for outpatient prescription drugs vary by state, and states have flexibility in whether they offer a prescription drug program and how they administer the program, although there are federal requirements related to the federal rebate program and reimbursement schedules (13). The Medicaid Drug Rebate Program (MDRP) requires drug manufacturers to enter into a rebate agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for coverage of the manufacturer's drugs by state Medicaid programs. In the MDRP, manufacturers are required to pay states a rebate for each unit of a drug covered by a state Medicaid program. The rebate is calculated by CMS and is based on either a percentage of the drug's average manufacturer price (AMP) or the lowest price available to wholesalers and other consumers. This enables states to get the best price offered to purchasers and to create a "best-price floor," whereby no purchaser is able to negotiate the price of a drug lower than the Medicaid price (14). Manufacturers are responsible for providing the price of the drug (either AMP or best price) and product information, including classification as an innovator or a noninnovator drug, to CMS. With some exceptions, manufacturers of innovator (single-source, typically brand-name) drugs are required to pay a rebate of either 23.1% of the AMP per unit or the difference between the AMP and the best price, whereas rebates for noninnovator (generic) drugs are 13% of the AMP per unit (15). As part of the Bipartisan Budget Act of 2015,

manufacturers are required to offer additional rebates if a drug's AMP exceeds the rate of inflation (16).

State and Federal Proposals to Decrease the Cost of Prescription Drugs

Although much of the public controversy surrounding the prices of Sovaldi (sofosbuvir), Daraprim (pyrimethamine), and the EpiPen and EpiPen Jr epinephrine injectors has died down, action taken at the federal level to reduce the price or cost of prescription drugs has primarily been incremental, and additional reforms from policymakers are necessary to drive down the costs of insulin, antibiotics, and other common prescription drugs that have seen large price increases that may make them prohibitively expensive for patients. The Bipartisan Budget Act of 2018 included 2 drug cost–related proposals: one to close the Medicare Part D coverage gap in 2019, a year earlier than scheduled, and the other to sunset the exclusion of biosimilar drugs in the coverage gap discount program. There has been considerable activity at the state level to address high drug pricing, with focuses on transparency, prevention of price gouging, and legislation related to pharmacy benefit managers, among other issues. A bill passed in Maryland would have required the state Medicaid agency to notify the attorney general of an excessive price increase for an essential generic medication or off-patent brand-name drug, with fines of up to $10 000 for violations (17). This law was struck down by the Fourth Circuit Court of Appeals on the grounds that it violated constitutional rights related to interstate commerce (18). Many bills have been introduced in Congress proposing solutions that include drug importation, intellectual property protections, and establishment of an interagency drug price review board (19). The House and Senate held 25 hearings between the 114th and 115th Congresses relevant to drug pricing, namely on price gouging or price spikes, investment in biomedical innovation, and reauthorization of the Prescription Drug User Fee Act (20).

President Trump made decreasing the cost of prescription drugs a central aspect of his 2016 campaign, and his administration has examined ways to keep prescription drug costs affordable for Americans. The administration has proposed several regulations to address the issue in the areas of price transparency and payment for drugs in government programs. Proposals from the White House, including the fiscal year 2019 budget proposal; those from the Council of Economic Advisers; and those from HHS have focused on lowering costs for patients, such as by passing on the rebates negotiated by pharmacy benefit managers to Medicare Part D beneficiaries at the pharmacy counter. In May 2018, President Trump unveiled "American Patients First," a set of policy priorities and suggested actions HHS may take to reduce out-of-pocket spending and decrease the list price of medications in 4 key strategy areas: improved competition, better negotiation, incentives for lower list prices, and lower out-of-pocket costs (21). Immediate actions include steps to promote biologics and prevent gamesmanship of the regulatory process, experimentation with value-based purchasing in federal programs, and development of proposals to stop price increases in the private market resulting from Medicaid or the Patient Protection and Affordable Care Act. The administration came out strongly against foreign governments that they believe take advantage of U.S. innovation by underpricing drugs, an idea also discussed in the White House Council of Economic Advisers white paper on reforming biopharmaceutical pricing and reflected in the administration's advanced notice of proposed rulemaking for an international pricing index for certain Medicare Part B drugs. The Council of Economic Advisers proposed using enhanced trade policies or policies that tie public reimbursements in the United States to prices paid by foreign governments (22). However, it is unclear how these and other proposals would be implemented or enforced.

Recommendations

1. ACP supports modification to the Medicare Part D low-income subsidy (LIS) program cost-sharing and copayment structures to encourage the use of lower-cost generic or biosimilar drugs, such as eliminating cost sharing for generic drugs for LIS enrollees.

Twelve million Medicare Part D beneficiaries are enrolled in the LIS program. Although use of low-cost generic drugs by Part D beneficiaries is relatively high and continues to increase as more generics become available, the generic drug use rate is lower among LIS enrollees than among other Medicare beneficiaries. The Medicare Payment Advisory Commission analyzed data on generic drug dispensing among LIS enrollees and non–LIS enrollees between 2009 and 2011 and found rates of 74% and 79%, respectively, in 2011 (23). An analysis of data by CMS showed a generic drug dispensing rate of 79.2% among LIS enrollees compared with 83.1% among non–LIS enrollees, with consistent differences between groups of 4% or 5% between 2006 and 2012 (23). Despite the current rate of generic drug dispensing among LIS enrollees and non–LIS enrollees, additional savings are possible for Medicare and its beneficiaries. The CMS estimates that Medicare could have saved nearly $9 billion if available equivalent generics were used instead of brand-name drugs and could have passed on $3 billion in savings to the Part D program and its beneficiaries (24).

Zero-copay generics have been shown to have the strongest effect on generic drug use for both LIS enrollees and non–LIS enrollees (25). Up to a $5000 total out-of-pocket maximum, LIS enrollees pay either $1.25 or $3.35 for generics and $3.70 or $8.35 for brand-

name drugs (26). The difference in price may not provide enough financial incentive for an LIS enrollee to choose a generic drug over a brand-name drug. Reducing or eliminating cost sharing for LIS enrollees would not require legislative action because it would not increase cost sharing, would reduce overall out-of-pocket costs for LIS enrollees, and would encourage use of generics among them. Reducing or eliminating cost sharing or copayments for generic drugs could also reduce Medicare spending on reinsurance payments because a majority of enrollees who reach the catastrophic phase of coverage are in the LIS program (24).

In addition to traditional generic drugs, biosimilar cost sharing should also ensure that LIS enrollees have an incentive to choose lower-cost alternatives to brand-name biologic drugs. Biosimilars have the potential to save $54 billion in direct spending on biologic drugs between 2017 and 2026 (27). The U.S. Food and Drug Administration (FDA) has approved 9 biosimilars for use in the United States. However, most approved biosimilars are delayed in coming to market by patent litigation or settlement agreements between the biosimilar and reference product manufacturing companies, and only 3 biosimilars are currently marketed in the United States (28). For example, Amjevita (adalimumab-atto), a biosimilar of the blockbuster biologic Humira (adalimumab), was approved in 2016 but will not come to market in the United States until 2023 (29), and a second biosimilar of Humira, Cyltezo (adalimumab-adbm), is tied up in litigation related to the extensive number of patents (also known as a patent estate) held for Humira. Despite the delay in bringing most biosimilars to market, payment and cost-sharing policies for approved indications of biosimilar drugs should be established now to inform pricing decisions and encourage use of these drugs as soon as they come to market.

2. ACP supports annual out-of-pocket spending caps for Medicare Part D beneficiaries who reach the catastrophic phase of coverage.

In 2016, Medicare beneficiaries spent an average of $3024 on out-of-pocket medical costs, including $756 (25%) on prescription drugs (30). Medicare beneficiaries can face substantial out-of-pocket costs for prescription drugs if they take costly specialty drugs and reach the catastrophic coverage phase. Between 2007 and 2015, the number of seniors in Medicare Part D who reached the catastrophic limit of coverage doubled to more than 1 million. In 2015, those enrollees paid an average of more than $3000 out of pocket, with 1 in 10 spending at least $5200, driven primarily by hepatitis C drugs (10). This group is likely to take higher-priced specialty medications (defined by Medicare as drugs with a negotiated monthly price above $670) for chronic conditions and may also take multiple drugs (10).

Non–LIS enrollees using certain specialty drugs for certain health conditions were more likely than those with other conditions to reach the catastrophic phase of coverage (31). Medicare beneficiaries have an average per capita income ranging from $13 650 to $30 050 depending on demographic characteristics. The high out-of-pocket costs associated with these specialty drugs can create barriers to access for these patients. In 2012, 96% of patients taking specialty drugs for multiple sclerosis hit the catastrophic phase of coverage, and 48% reached that phase by the end of February. In 2008, only 4% of patients taking multiple sclerosis drugs reached the catastrophic phase by the end of February (32). An analysis of specialty drugs showed that the retail price of the multiple sclerosis drug Avonex (interferon β1) increased by 333.5% (from $17 438 to $75 595) between 2005 and 2015 (31).

Policymakers should implement caps on out-of-pocket expenses for prescription drugs in the catastrophic phase of coverage to protect vulnerable seniors from being exposed to increased financial burden. Caps have been proposed in other areas of Medicare; a 2016 resolution from the House Committee on the Budget included a Medicare proposal with a catastrophic coverage cap on annual out-of-pocket expenses, which it called, "an important aspect of the private insurance market currently absent from Medicare that would safeguard the sickest and poorest beneficiaries" (33). Policymakers should also consider how to mitigate or minimize potential unintended consequences of a cap, such as reforming the structure of Medicare's reinsurance subsidy or modifying the Part D risk adjustment algorithm, without placing additional cost burdens on beneficiaries.

3. ACP supports the adoption of Medicare Part D negotiation models that would drive down the price of prescription drugs for beneficiaries.

a. While ACP reaffirms its support for a full repeal of the noninterference clause, ACP also supports an interim approach, such as allowing the Secretary of Health and Human Services (HHS) to negotiate for a limited set of high-cost or sole-source drugs.

b. ACP supports a public Medicare Part D plan option that allows the Secretary of HHS to negotiate prices with drug makers. Any Medicare-operated public plan must meet the same requirements as private plans and be consistent with ACP's policy on formularies.

Allowing Medicare to leverage its purchasing power and negotiate the price of drugs in the Part D program directly with pharmaceutical manufacturers has been debated since the enactment of the MMA in 2003 (34). Negotiation was considered for inclusion, but the bill ultimately included a noninterference clause, which strictly prohibited HHS from "[interfering] with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors" and

from "[requiring] a particular formulary or [instituting] a price structure for the reimbursement of covered part D drugs," as a way to encourage market competition (35). Opponents of a repeal of the noninterference clause claim that the current system works well and that spending in the program was below initial projections. However, reports by the Congressional Budget Office, the HHS Office of Inspector General (OIG), and the Government Accountability Office have found that the Medicaid program, which imposes mandatory federal rebates, is able to secure lower average drug prices than those in Part D (36, 37).

A 2007 Congressional Budget Office assessment of repealing the noninterference clause found that there would be modest cost savings if the government were able to negotiate, stating that the government would not be able to secure better prices than those already being negotiated without formulary restrictions, similar to what is done by the Department of Veterans Affairs or in other specific circumstances, such as for sole-source drugs with no market competition (38). However, other estimates put potential savings much higher (up to $16 billion per year) if the government were able to negotiate for Part D drugs and achieve the same prices as the Department of Veterans Affairs or Medicaid (39). Granting Medicare Part D the authority to negotiate drug prices is favored by a bipartisan majority of the public, with more than 90% of Democrats, Republicans, and Independents agreeing with this approach (40). Negotiating authority was also endorsed in a report by the National Academies of Sciences, Engineering, and Medicine on improving the affordability of prescription drugs as part of a package of broader reforms for consolidating and leveraging purchasing power and strengthening formulary design (41).

Determining how and to what extent Medicare should negotiate drug prices is complex, and policymakers have begun to consider the scope of government negotiation power. In one proposal, researchers set forth 3 key issues to consider when assessing Part D negotiation proposals: which drugs HHS would have authority to negotiate, whether HHS could negotiate both price and formulary design, and whether the negotiated terms would apply to all Part D plans (42). A proposal that emerged during the Obama administration would allow HHS to negotiate for a limited set of high-cost and biologic drugs (43). Senator Bernie Sanders's Medicare for All Act would give the federal government monopsony power to negotiate prescription drug prices with pharmaceutical manufacturers (44).

The ACP has long-standing policy supporting the ability of Medicare to leverage its purchasing power and negotiate drug prices directly with manufacturers and continues to support repeal of the noninterference clause. Although negotiation alone may not be enough to rein in drug prices, this approach would allow the government to leverage its purchasing power to reduce Medicare program costs while also allowing plan sponsors to maintain the power to negotiate for the vast majority of drugs covered in the program. Absent repeal, the noninterference clause should be modified to allow for this type of negotiation by the government for high-cost drugs in which Medicare has substantial financial interest.

Another proposal is to create a public option Part D plan in which the Secretary of HHS negotiates drug prices within the plan and has authority over the formulary alongside private plans. This type of plan would operate in the same way as private plans but would allow the government the option of excluding certain drugs from the formulary as long as they meet minimum mandated coverage benefits required by other plans and in a way that is consistent with ACP policy on formularies. An examination of the potential effect of such a plan showed some competitive market benefits (45). This approach may be limited in scope because it would only benefit those who choose the plan and potential formulary exclusions may cause issues related to the safety-net nature of Medicare (46). A public plan approach should be tested before any wide-scale rollout.

4. ACP supports efforts to minimize the financial impact on the federal government of prescription drug misclassification in the Medicaid Drug Rebate Program (MDRP). The Centers for Medicare & Medicaid Services should identify which legal authorities are necessary to ensure compliance with the MDRP and Congress should pass legislation to grant such authorities.

Misclassifications in the MDRP can increase the share of spending on prescription drugs and can divert monies from other programs and services. In response to a request by Congress, the OIG conducted a study of misclassifications in the MDRP and found that manufacturers may have misclassified 885 of the 30 000 drugs in the program (47). Ten misclassifications between 2012 and 2016 may have cost Medicaid $1.3 billion in lost base and inflation-adjusted rebates, and 4 manufacturers were associated with more than half of misclassifications (47). Two drugs, the EpiPen and EpiPen Jr autoinjectors, were improperly classified as generic drugs for the purposes of the program, although they lacked any FDA-approved equivalent. The maker of the EpiPen, Mylan, recently entered into a $465 million settlement agreement with the Department of Justice to settle claims related to the False Claims Act for knowingly misclassifying the EpiPen to avoid paying rebates (48). The False Claims Act is used to pursue cases in which the federal government has been defrauded by a private party.

Outside pursuing relief under the False Claims Act, the OIG claims that HHS does not have explicit legal authority to require manufacturers to change data identified as being misclassified, and oversight of the pro-

gram has been weak. The OIG recommends that CMS "pursue a means to compel manufacturers to correct inaccurate classification data reported to the Medicaid rebate program" and suggests that CMS could seek legislative authority to compel manufacturers to submit accurate data or enhance current data (47). Key Congressional committee chairs recently sent a letter to CMS Administrator Seema Verma expressing concern about misclassifications and requesting additional information on CMS's authorities and oversight of the program (49). Granting CMS the authority to compel manufacturers to change classification data and supporting enhanced oversight of the program will ensure that state Medicaid programs receive proper rebates for prescription drugs and will minimize potential disruptions to access to drugs among Medicaid beneficiaries.

5. ACP supports further study of payment models in federal health care programs, including methods to align payment for prescription drugs administered in-office in a way that would reduce incentives to prescribe higher-priced drugs when lower-cost and similarly effective drugs are available.

Medicare Part B payment for a physician-administered drug is tied to the price of the drug, which may contribute to companies setting high list prices for these drugs and may provide greater incentive to prescribe more expensive drugs, even if there are lower-cost, similarly effective alternatives that would be tolerated by the patient. In 2016, CMS proposed testing changes to payment for prescription drugs in Medicare Part B in a nationwide demonstration project through the Center for Medicare & Medicaid Innovation. The project would have changed the current ASP+6% payment for Part B medicines to an ASP+2.5% payment and a flat fee during the initial phase of the project and would have tested value-based purchasing, such as reference pricing or indication-based pricing, in the second phase. The project sparked public backlash, particularly from pharmaceutical companies and some medical societies, based on Medicare data indicating that patient access would be better under Part B than the formula proposed by the demonstration. The project was officially withdrawn in July 2017 (50). The ACP's comments on the proposed rule expressed concerns about the first phase of the project, particularly the financial burden that the change may have placed on small or solo practices, and urged CMS to reconsider the scope of the demonstration (51).

Several alternatives to the ASP+ payment model have been suggested. One proposal would have moved payment for some drugs from Part B to Part D (52). Another called for enhanced ASP data reporting, modifications to the payment rate for drugs paid at the wholesale acquisition cost, a requirement for manufacturers to pay Medicare a rebate when the ASP exceeds an inflation benchmark, consolidation of billing codes, and negotiation between vendors and manufacturers on behalf of physicians (53). A third proposal suggested eliminating the connection between price and payment, and another advocated for establishment of 2 payment options, with Medicare paying the lower option for a particular drug (54). Further study of these and other proposals is needed to establish whether they truly would result in cost savings, their potential effect on physician practices of varying size, whether they would affect patient access, and potential unintended consequences. Demonstration projects or pilots that result from proposals should be developed with robust stakeholder input (including from physicians), should be appropriately scaled, and should have safeguards in place to ensure patient access to medications.

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