High-visibility complaints about escalating drug prices continue to make headlines, propped up by the introduction of very expensive cancer and specialty drugs, such as the new chimeric antigen receptor (CAR) T-cell therapy drugs tisagenlecleucel (Kymriah, Novartis Pharmaceuticals Corp.) and axicabtagene ciloleucel (Yescarta, Kite Pharma, Inc.). Less noticeable have been quiet Trump administration changes in federal health programs, such as Medicare, which make minor but significant consumer-friendly changes in the way drugs are priced for seniors in 2019 and lay the groundwork for more radical changes in the future.

Eye-popping price hikes for existing drugs and stratospheric prices on some new specialty drugs continue to catch the attention of Washington power players, such as Rick Pollack, President and Chief Executive Officer (CEO) of the American Hospital Association, and Jo Ann Jenkins, CEO of AARP, the seniors’ lobby. They co-wrote an opinion piece in the April 23 edition of The Hill, the major Capitol Hill daily newspaper, citing two recent troubling studies on the extent to which drug prices have increased.

They went on to say: “More specifically, from 2012 to 2017, twelve out of the 20 most commonly prescribed brand-name drugs for seniors had their prices increased by over 50% while six out of the top 20 had prices increases of more than 100%.”

Congress is beginning to pay a little attention to those complaints, but the Centers for Medicare and Medicaid Services (CMS) has quietly begun to take what could be described as aggressive though limited action to knock down drug prices. Final rules for the Medicare Part D outpatient drug program and the Patient Protection and Affordable Care Act (PPACA) insurance exchanges make some inroads into how insurance and the Patient Protection and Affordable Care Act (PPACA) insurance exchanges make some inroads into how insurance and the Patient Protection and Affordable Care Act (PPACA) insurance exchanges are regulating the landscape of drug pricing and pharmacy access. Another pharmacy pricing issue Congress may have a say on is pharmacy gag orders where PBMs and insurance companies bar pharmacists from telling customers that it would be cheaper to pay for a prescription out-of-pocket as opposed through insurance. The Patient Right to Know Drug Prices Act would ban that practice, which a number of states have already outlawed. That bill (S. 2554) and a counterpart (S. 2553)—one addresses Medicare, the other the PPACA insurance exchanges—are sponsored by Democrats and Republicans in the Senate, which bodes well for progress through the Congress.

That reference to “value-based care” appears to apply to IPPS reimbursement for drugs beyond those two new CAR-T therapies, which were approved by the FDA in 2017.

Novartis spokeswoman Dana Cooper says tisagenlecleucel’s cost for patients up to 25 years of age is $475,000; for a second indication the FDA approved in April for the treatment of adult patients with relapsed or refractory large B-cell lymphoma, the cost is $373,000. Sales for the treatment were $12 million in the first quarter of 2018, based on sales from the pediatric indication, which is made up of an extremely small patient population.

However, those final and proposed CMS drug pricing rules for calendar 2019 don’t wade in to the more controversial areas the CMS is considering making changes in: point-of-sale price concessions for Part D and a federal default drug plan for the federal exchanges.

Medicare final and proposed rules aren’t necessarily the end of the discussion on drug pricing and access issues. Drug counter rebates could come into play in 2018 because President Donald Trump’s fiscal 2019 budget request would require Part D plans to pass on at least one-third of total rebates and price concessions to enrollees at the point of sale. The government’s fiscal 2019 budget goes into effect, theoretically (if Congress passes one in time), on October 1, 2018. Congress will have a chance to approve that controversial change—even though the CMS has punted on it in the 2019 Part D final rule.

That possibility illustrates the unsettled nature of federal requirements with regard to drug pricing and access. Another pharmacy pricing issue Congress may have a say on is pharmacy gag orders where PBMs and insurance companies bar pharmacists from telling customers that it would be cheaper to pay for a prescription out-of-pocket as opposed through insurance. The Patient Right to Know Drug Prices Act would ban that practice, which a number of states have already outlawed. That bill (S. 2554) and a counterpart (S. 2553)—one addresses Medicare, the other the PPACA insurance exchanges—are sponsored by Democrats and Republicans in the Senate, which bodes well for progress through the Congress.

Part D Changes

The Medicare Part D outpatient drug program plays an outsized role in steering drug cost and pharmacy access issues generally given that decisions made by Medicare are often adopted in the commercial marketplace. The CMS takes incremental steps in 2019 in areas such as tiering exceptions, medication therapy management programs, utilization management procedures within new drug management programs meant to address overuse of opioids, and formulary substitutions.
Medicare Quietly Forces Changes to Federal Formulary Requirements

One of the most controversial issues for plans in 2019 was whether the agency should order PBMs and Part D plans to pass through to consumers a portion of the rebates they receive from manufacturers for each prescription purchased by the consumer at the pharmacy. The CMS did not appear to be seriously considering a mandate for 2019; it just wanted to get a feel for how the pharmacy distribution chain felt about the concept. The PBMs hate it, insurance companies hate it a little less, and drug manufacturers are all for it, as are consumer groups for the most part.

The Pharmaceutical Care Management Association, which represents the PBMs, was vehement in its opposition, arguing any mandated point-of-sale (POS) rebate would violate at least four separate provisions of the Part D statute as well as the Trade Secrets Act. The CMS itself admitted mandated rebates would cost the Medicare program tens of billions of dollars over the next 10 years. America’s Health Insurance Plans (AHIP), the health insurance company lobby, said talk of pharmacy counter price concessions “misses the mark by focusing on approaches that fail to address the root problem: excessive list prices for drugs and excessive price increases that are set solely by and fully within the control of manufacturers.”

While no Part D mandate on pharmacy price concessions was offered, the CMS said it would “continue our efforts to meaningfully address rising prescription drug costs for beneficiaries” and pointed to President Trump’s budget proposal. And in what was probably a warning to the PBMs, the agency said its statutes “provide us with discretion to require that Part D sponsors apply at least a portion of the manufacturer rebates and all pharmacy price concessions they receive to the price of a Part D drug at the point of sale.” In other words, the CMS doesn’t need congressional approval to order rebates to Medicare recipients.

A separate POS issue—though in a different context—came up in the context of the new drug management programs (DMPs) Part D plans are expected to adopt in 2019. These DMPs are the result of a provision in the 2016 Comprehensive Addiction and Recovery Act meant to address the opioid crisis.\(^5\) Adoption of DMPs will be voluntary, but the CMS expects plans to implement them for a variety of reasons. The programs will allow plans to limit an at-risk beneficiary’s (there is a definition for that in the final rule) access to coverage of frequently abused drugs beginning in 2019 through a beneficiary-specific POS claim edit and/or by requiring the beneficiary to obtain frequently abused drugs from a selected pharmacy and/or prescriber(s) after case management and notice to the beneficiary. To do so, the beneficiary will have to meet clinical guidelines that factor in that the beneficiary is taking opioids over a sustained time period and that the beneficiary is obtaining them from multiple prescribers and/or multiple pharmacies. The P&T committees in each plan will be responsible for approving the DMP, which must include at least (as a minimum): 1) the appropriate credentials of the clinical staff conducting case management; 2) the necessary and appropriate contents of files for case management, which must include documentation of the substance of prescriber and beneficiary contacts; and 3) monitoring reports and notifications about incoming enrollees who meet the definition of an at-risk beneficiary or a potential at-risk.

The 2019 Part D rule gives a boost to medication therapy management (MTM) programs—which promote therapy adherence and lower patient costs generally, both for plans and Medicare—by affirming that MTM programs qualify as quality improvement programs, which then allows a Part D plan to include the costs of the program in the numerator of its medical loss ratio (MLR) calculation. Companies are required to keep MLRs above a certain percentage by maximizing what they spend on patient care versus administrative expenses. All Part D plans already are required to have MTM programs in place, but the CMS rules give plans leeway as to how aggressive to be in finding potential enrollees by, in one instance, fulfilling an obligation to conduct comprehensive medical reviews for plan members meeting certain criteria, criteria the plans establish within certain prescribed bounds. Generally, these MTM plans vary widely as to their reach and effectiveness and to the extent they are underutilized, which is the CMS’ contention, that has to do with their cost Medicare says in the final rule “we have expressed concern that Part D sponsors may be restricting MTM eligibility criteria to limit the number of qualified enrollees.”

Drug price suppression for Medicare beneficiaries does come into play in the Part D final rule via a fairly substantial change in formulary policy for 2019: allowing Part D plans to immediately substitute a newly available generic equivalent for a brand-name drug. The past policy required a 60-day notice prior to the substitution. Some patient groups, such as the American Heart Association, and drug manufacturers, such as Pfizer, either opposed the change or wanted it modified, especially with regard to the elimination of an advance warning to plan members that they would henceforth be receiving a generic and not the brand-name drug. The CMS swatted away that concern, including dismissing the argument that the National Association of Insurance Commissioners model guidelines on Health Carrier Prescription Drug Benefit Management Act (#22) required a minimum 60-day advance notice for both generic and nongeneric substitutions.\(^6\) The agency said that a requirement that plans tell members up front that generic substitutions may be made without warnings was sufficient and that patients generally understand the prevalence of the practice, which saves money and does not harm safety.

The final Part D rule includes an extensive discussion about formulary tiering and exceptions to it, including whether multisource drugs and other drugs that do not meet the definition of a generic or authorized generic drug that a plan may place on a generic-labeled tier can be treated as generic drugs for purposes of tiering exceptions. The CMS did revise the tiering exceptions regulations to specify that authorized generic drugs should be treated as generic drugs. But it declined to go further than that.

Lastly, Part D 2019 policy makes it harder for plans to exclude a tier containing alternative drug(s) with more favorable cost-sharing from their tiering exceptions procedures altogether just because that lower-cost tier includes only generic drugs. The final rule says:

Under our proposal, plans would be required to approve tiering exceptions for non-preferred generic drugs when the plan determines that the enrollee cannot take the preferred generic alternative(s),
including when the preferred generic alternative(s) are on dedicated generic tier(s) and when the lower tier(s) contain a mix of brand and generic alternatives.

The final rule would permit plans to limit the availability of tiering exceptions for brand-name drugs and biological products, including biosimilar and interchangeable biological products, to a preferred tier that contains the same type of alternative drug(s) for treating the enrollee’s condition. The objective is to ensure that tiering exceptions result in drugs being generally assigned to the lowest applicable cost-sharing levels.

But what constitutes an “alternative” drug for the purpose of a tiering exception? The CMS clarifies that an alternative drug for tiering exception purposes is a drug on a lower cost-sharing tier that is appropriate for treating a beneficiary, taking into consideration the facts and circumstances of the individual’s specific clinical condition, including comorbidities and characteristics of the enrollee and/or drug regimen.

The AHIP wanted the CMS to be more exacting in defining “alternative.” It was concerned that “an inappropriately broad interpretation of the tiering exception policy would be inconsistent with the legislative intent and would also substantially inhibit the proven ability of Part D plans to use formulary tiering as a means of ensuring cost-effective Part D coverage for beneficiaries.” It asked the CMS to offer further clarity of what constitutes an “alternative” drug by producing sufficient examples of “alternatives” to nonpreferred drugs in the final regulation and through subregulatory processes (i.e., updates to the Medicare Prescription Drug Benefit Manual and annual Medicare Advantage and Part D Call Letter).

PPACA Plans in 2019

The CMS has considerably less wiggle room when it comes to pharmacy prices and formulary dictates in the PPACA Exchange program (sometimes referred to as Obamacare plans) than it does with regard to the Part D program. That said, the CMS created a stir when it said it was considering creating a national benchmark plan for prescription drugs, one of the 10 categories of essential health benefits (EHB) every insurer offering marketplace plans must offer. Currently, each state creates its own drug benchmark plan, and they differ markedly from state to state. But every state plan must meet one of two baseline standards: 1) one drug in every United States Pharmacopeia category and class, or 2) the same number of prescription drugs in each category and class as the EHB benchmark plan. There are additional requirements, too, related to P&T committees, exceptions for drugs not on a formulary, appeals to plans, and other issues. Each Exchange plan in each state can exceed its state pharmaceutical benchmark standard and can substitute drugs within any category as long as it meets the number of drugs in that category in the benchmark plan.

The state benchmark plan is a floor in each of the 10 categories. Qualified health plans in each state can enrich their offering in any or all of the 10 categories, including pharmaceuticals. The impetus for a potential national pharmaceutical benchmark, which all states would have to adhere to, is the CMS’s apparent thinking, not made clear in writing, that a national drug access standard would give the agency the ability to select less expensive options in categories, which might pressure state Exchange plans to follow suit. The big insurers are more likely to be open to a national benchmark drug plan because they and the PBMs that serve them, with clients in numerous states, have a hard time developing different formularies for different states.

The CMS did not have much to say about a national prescription drug EHB benchmark in the final rule. The idea elicited strong opposition when it was raised in the proposed rule. However, the final rule gives states some significant leeway with regard to how they structure their 10 EHB categories. The final rule allows a state to change its EHB benchmark plan by: 1) selecting the EHB benchmark plan that another state used for the 2017 plan year; 2) replacing one or more EHB categories of benefits under its EHB benchmark plan used for the 2017 plan year with the same categories of benefits from another state’s EHB benchmark plan used for the 2017 plan year; or 3) otherwise selecting a set of benefits that would become the state’s EHB benchmark plan, provided that the EHB benchmark plan does not exceed the generosity of the most generous plan among a set of comparison plans.

States have to notify the CMS by July 2, 2018, if they plan to take advantage of this new benefit substitution policy in plan year 2020. That may be too tight a deadline for many states that could put off making any changes until 2021. Kelly Brantley, Vice President of Avalere Health, says state A could take the prescription drug offering from the benchmark plan offered by state B. However, she notes an analysis that Avalere did on the 2014 benchmarks showed that exchange plan breadth of formulary coverage did not vary substantially from state to state, even when benchmark plan formularies did vary considerably.

Hospital Inpatient Proposed Rule

The CMS proposed rule for how it will reimburse hospitals in 2019 contains an option of drug pricing for the two new CAR T-cell therapy drugs. The agency sought comments on a payment methodology alternative that might be better than the technology add-on payments both Novartis and Kite have sought for their two new drugs. Medicare awards technology add-on payments when the diagnosis-related group (DRG) rate is inadequate.

Rather than approve the add-on payment, the CMS is considering creating a new Medicare Severity (MS)-DRG for procedures involving the utilization of CAR T-cell therapy drugs. Cases representing patients receiving treatment involving CAR T-cell therapy to the agency could be assigned ICD-10-PCS procedure codes XW033C3 and XW043C3, effective for discharges occurring in FY 2019. These payment alternatives, including payment under any potential new MS-DRG, could also take into account an appropriate portion of the average sales price for these drugs, including in the context of the pending new technology add-on payment applications. It isn’t clear how this alternative would affect the $470,000 and $375,000 costs for tisagenlecleucel’s two indications, for example.

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the proposed changes to the CMS Medicare IPPS, and is planning to submit a full response during the comment period.”

FDA Commissioner Scott Gottlieb, MD, appears to be the Trump administration’s leading public advocate for lowering prescription drug prices, if national headlines are any indication. But it is the CMS that is actually putting somewhat significant though so-far limited policies in place and warning that upcoming rulemakings may seek to establish what PBMs and insurance companies would surely view as more threatening actions. What the CMS and Dr. Gottlieb have avoided to date, however, is any action aimed directly at what many view as drug company inflated pricing.

REFERENCES


