EXECUTIVE SUMMARY

At the 2011 Interim Meeting, the House of Delegates referred Resolution 802, which was introduced by the American College of Rheumatology. The Board of Trustees assigned this resolution to the Council on Medical Service for a report back to the House of Delegates at the 2012 Interim Meeting. Resolution 802-I-11 asked that our American Medical Association (AMA) assist in passing federal and/or state legislation to reverse insurance policies that increase co-pays/coinsurance by a percentage for a subset of patients that need to have these critical medications, and update the previous Council reports on tiered drugs to specifically analyze how higher insurance co-pays/coinsurance not only decrease access to care but cost society in the long run with lost days of employment, long term disability and the overall cost of the support of patients with chronic illnesses needing these drugs.

While pharmacy benefit designs are often used with the goal of controlling the costs of prescription drugs, the Council believes that a key goal of pharmacy benefit designs should be to improve patient treatment and adherence. The purpose of cost-sharing for prescription drugs in general should be to encourage the judicious use of health care resources, rather than simply shifting costs to patients.

Adherence by patients to treatments involving specialty drugs is especially critical, because noncompliance with their treatment regimens can lead to worsening of symptoms or disease, hospitalizations and other costly interventions. As advocated by AMA policy, pharmacy benefit designs should prioritize value in health care spending using targeted benefit design, whereby patient cost-sharing requirements are reduced for maintenance medications used to treat chronic medical conditions. The Council notes specialty drugs are particularly suited to targeted benefit design, which would promote their efficient and effective use.

Health plan transparency is important for physicians and patients, who need price and out-of-pocket cost information about prescription drugs prior to making prescribing decisions. In addition, patients need education and assistance with health plan selection so that they are aware of covered services, cost-sharing obligations, out-of-pocket limits, lifetime benefit caps, and excluded services.

The Council recommends reaffirming AMA policies related to targeted benefit design, the appropriate use of cost-sharing arrangements for prescription drugs, health plan transparency, and patient education and assistance.
At the 2011 Interim Meeting, the House of Delegates referred Resolution 802, which was introduced by the American College of Rheumatology. The Board of Trustees assigned this resolution to the Council on Medical Service for a report back to the House of Delegates at the 2012 Interim Meeting. Resolution 802-I-11 asked:

That our American Medical Association (AMA) assist in passing federal and/or state legislation to reverse such insurance policies that increase co-pays/coinsurance by a percentage for a subset of patients that need to have these critical medications; and

That our AMA update the previous Council reports on tiered drugs to specifically analyze how higher insurance co-pays/coinsurance not only decrease access to care but cost society in the long run with lost days of employment, long term disability and the overall cost of the support of patients with chronic illnesses needing these drugs.

This report provides background on specialty drugs, outlines pharmacy benefit design strategies to control the costs associated with the coverage of specialty drugs, provides a summary of legislative and regulatory activity, summarizes relevant AMA policy, and presents policy recommendations.

BACKGROUND

Patients, physicians, employers and health plans are facing the increasing financial burden posed by specialty drugs, including biologic medications and chemotherapies. Specialty drugs are used to treat chronic and complex conditions including cancer, rheumatoid arthritis and multiple sclerosis. Most specialty drugs are biologic in nature – derived from living sources such as humans, animals or microorganisms. Whereas most specialty drugs have historically been administered by infusion or injection, a growing number of oral and inhaled drugs have entered the specialty drug category. In 2008, spending on specialty medications (in 2010 dollars) averaged $11,746 per user of such drugs covered by a group of large commercial health plans. The reported spending included both patient cost-sharing and health plan payment. On the whole, prescription drugs account for approximately 10 percent of total health spending, and biologics make up nearly 20 percent of drug spending.

Overall prices for specialty drugs are higher resulting from the high risk and expense of manufacturing the drugs, the special handling and administration required for the drugs, and an overall lack of competition in the marketplace. Within most therapeutic categories in which specialty drugs are offered, there are often few or no substitutes, and the available substitutes tend
to be imperfect. Currently, drug manufacturers have 12 years of market exclusivity for innovator products. Innovator drugs also have additional patent protection that generally exceeds the market exclusivity period by a few years. Because manufacturers normally pass on some development costs to patients, the reality that a small percentage of patients are in need of specialty drugs translates into these patients absorbing a higher percentage of development costs per user.

Specialty drugs are covered under both the pharmacy and medical benefits of commercial and government health plans. Specialty drugs that are self-administered are usually covered under the pharmacy benefit of health plans, including Medicare Part D. However, specialty drugs that are furnished and administered by physicians in clinical settings are covered under the medical benefit, including Medicare Part B. Specialty drugs covered under the medical benefit account for a substantial share of total spending on such drugs. In commercial health plans, approximately 55 percent of total spending on specialty drugs is spent under the medical benefit. Under Medicare Part B, spending for prescription drugs was approximately $18.6 billion in 2010. The drugs with the highest Part B spending were biologic drugs.

Specialty drugs account for a larger proportion of prescription drug spending by both commercial plans and Medicare, despite the low percentage of enrollees receiving such drugs. Twelve to 16 percent of commercial health plan prescription drug spending is directed toward specialty drugs, while such drugs are prescribed to only one percent of health plan enrollees. Monthly spending in a commercial health plan per patient usually is greater than $1,200 for a specialty drug. In 2007, drugs eligible for the specialty tier in Medicare Part D plans accounted for 10 percent of prescription drug spending under the plans.

TIERING VS. VALUE-BASED BENEFIT DESIGN

Government and private health plans are using various benefit design strategies to control their costs associated with the coverage of specialty drugs. One of the leading strategies, four-tier pharmacy benefit design, is common in Medicare Part D, and many employers have followed suit. With a four tier design, many specialty drugs are assigned to the fourth tier, also called a “specialty tier,” which generally has much higher cost-sharing for patients. Patients in need of fourth tier drugs commonly have to pay coinsurance – and pay a percentage of the total drug costs – versus defined copayments. Coinsurance in the fourth tier can range from 10 percent to 35 percent of the cost of the specialty medication. Although out-of-pocket maximums are often in place, and some subsidies may be provided by drug companies, transitioning from the third to the fourth tier represents a significant increase in cost-sharing for patients.

According to the 2011 Employer Health Benefits Survey from the Kaiser Family Foundation and the Health Research and Educational Trust (KFF/HRET), 77 percent of covered workers are in plans with three or more tiers of cost-sharing for prescription drugs. Fourteen percent of covered workers are in plans with four or more tiers of cost-sharing. Of the workers in plans with four or more cost-sharing tiers, 36 percent have copayments for fourth-tier drugs and 24 percent have coinsurance. The average copayments in plans with three or four tiers are $10 for first-tier drugs, $29 for second-tier drugs, $49 for third-tier drugs, and $91 for fourth-tier drugs. The average coinsurance for a fourth-tier drug is 29 percent.

The four-tiered design is the most common approach to tiered cost-sharing for prescription drugs under Medicare Part D. In Medicare Part D, specialty tiers are used for those drugs with expenses of at least $600 per month. In 2011, among enrollees in Part D plans that use tiered cost-sharing, 94 percent of enrollees in Part D stand-alone prescription drug plans were in plans with a specialty tier, and 100 percent of enrollees in Medicare Advantage prescription drug plans were in plans with
a specialty tier. CMS limits the coinsurance rate for drugs on specialty tiers to 25 percent, but plans can have higher coinsurance amounts for drugs in the specialty tier if such cost-sharing is offset by a lower deductible. Therefore, coinsurance rates in specialty tiers under Part D range from 25 to 33 percent. In 2011, roughly half of enrollees in stand-alone Medicare Part D plans and more than three-fourths of enrollees in Medicare Advantage prescription drug plans were in plans with a coinsurance rate for specialty drugs of 33 percent in the initial coverage period.

A leading alternative to cost-based, four-tier pharmacy benefit design is the use of value-based benefit design for prescription drug cost-sharing. While patients have to pay more for more expensive specialty drugs under four-tier pharmacy benefit design regardless of a drug’s value and effectiveness, patient cost-sharing under value-based benefit design is based on the clinical value of the specialty drug. As outlined in CMS Report 1-I-07, Cost-Sharing Arrangements for Prescription Drugs, which established Policy H-110.990, value-based benefit design considers the effect of patient compliance on health outcomes. Using varying levels of out-of-pocket cost-sharing to reward compliance by patients with chronic conditions, value-based benefit design averts costly adverse outcomes. Therefore, patient cost-sharing for prescription drugs could be reduced or eliminated to encourage treatment adherence for those drugs deemed to have high value.

To date, however, value-based benefit design has primarily focused on services and medications that have clear value. For example, value-based benefit design has been used to reduce or eliminate the cost-sharing for insulin to manage diabetic patients. The Council recognizes that expanding the use of value-based benefit design to all specialty drugs requires the development of criteria that determine which specialty drugs have high value, and the patients for which said drugs would have high value. Therefore, the value of specialty drugs would depend partly on patient characteristics, including clinical indication, disease severity and comorbidities. The Council believes that comparative effectiveness research, including research funded by the Patient-Centered Outcomes Research Institute (PCORI), has the potential to play a key role in determining which specialty drugs work best for which patients.

The Council notes that value-based benefit design could also be incorporated into a four-tier pharmacy benefit design. In such a scenario, specialty drugs of high value could be moved from the fourth to the second cost-sharing tier, whereby patient cost sharing could change, from potentially paying a percentage of total drug costs in the form of coinsurance, to a more modest copayment. Alternatively, there could be fourth and fifth tiers of specialty drugs. The fourth tier would be dedicated to specialty drugs with high value, which therefore would have a lower coinsurance rate than specialty drugs in the fifth tier, which would include more low-value drugs.

Another alternative is the use of income-based benefit design, whereby cost-sharing levels for prescription drugs vary by patients’ earnings so that cost-sharing for specialty and other prescription drugs would be tied to what the respective patients can afford. Some employers that have implemented income-based benefit design have added tiers of cost-sharing to their tiered pharmacy benefits. For example, for second-tier drugs, employees with the lowest incomes pay lower co-payments than their colleagues with higher incomes. Other variances in cost-sharing for prescription drugs can include varying deductibles and out-of-pocket maximums based on income. The Council notes that difficulties using this approach in the employer-sponsored insurance market can arise as employers may be restricted to assigning their employees to cost-sharing tiers based on their salaries versus their household incomes. However, lessons can be learned from employers that have historically tied employee premium contributions to income.
Different manifestations of income-based benefit design exist in the Medicaid and Medicare programs, as well as the health insurance exchanges that are scheduled to be implemented in 2014. In the Medicaid program, individuals with incomes above 150 percent of the federal poverty level (FPL) have the potential to pay as much as 20 percent of the cost of non-preferred drugs. However, individuals with incomes at or below 150 percent FPL pay small copayments for non-preferred drugs. In Medicare Part D, subsidies are provided to low-income Medicare beneficiaries to limit Part D cost-sharing, which results in these individuals facing less cost-sharing for prescription drugs than their higher-income counterparts. Finally, for qualified health plan coverage offered through health insurance exchanges, cost-sharing subsidies will be provided to eligible individuals and families with incomes between 100 percent and 400 percent FPL. These cost-sharing subsidies would reduce their cost-sharing amounts and annual limits on cost-sharing.

LEGISLATIVE AND REGULATORY ACTIVITY

There has been legislative activity on the state and federal levels addressing specialty tiers. In 2010, New York became the first state to enact a law that prevents health insurance plans from creating specialty drug tiers. A number of states have introduced or are considering introducing legislation addressing specialty tiers as well as patient out-of-pocket liability for prescription drugs. On the federal level, Representative McKinley (R-WV) has introduced H.R. 4209, the Patients’ Access to Treatments Act of 2012, which would require commercial health insurers to require defined copayments rather than percentage coinsurance for specialty tier medications.

The Patient Protection and Affordable Care Act (ACA, PL 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, PL 111-152) contained some provisions addressing the affordability of prescription drugs, including biologics. The law included provisions that improve the affordability of prescription drugs for beneficiaries in the so-called Medicare Part D “donut hole,” with affected beneficiaries paying less in the donut hole until the donut hole is eliminated by 2020. Additional provisions in the ACA address cost-sharing for health insurance coverage and essential benefits, under which prescription drugs fall. The ACA limits the out-of-pocket cost-sharing for essential benefits that individuals would be required to pay. The ACA specified that the essential health benefits package must cover the category of prescription drugs. The ACA caps the out-of-pocket liability for individuals and families with incomes between 100 percent FPL and 400 percent FPL based on income. Finally, eligible individuals and families with incomes between 100 percent FPL and 400 percent FPL can receive cost-sharing subsidies for coverage offered in health insurance exchanges.

In addition, the ACA included a subtitle (Biologics Price Competition and Innovation Act of 2009) that establishes an abbreviated approval pathway for products that are “highly similar” (i.e., biosimilar) to, or further demonstrated to be “interchangeable” with a Food and Drug Administration (FDA)-licensed biologic product. The AMA has consistently supported a set period of FDA conferred market exclusivity for regulated drugs in order to incentivize innovation and to allow reference manufacturers to recover their research costs and investment. While the FDA had legal authority to approve generic drugs, it was not until the passage of the ACA that the agency had legal authority to approve comparable or interchangeable biosimilars. The AMA was a strong supporter of ACA provisions conferring the FDA with the authority to establish a biosimilar approval pathway. The FDA is now working to establish an approval pathway for biosimilars. In addition, the recently passed Biosimilar User Fee Act of 2012 (which was part of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144)) ensures adequate FDA funding for timely review and approval, as appropriate, of biosimilar applications. The Obama administration, in its fiscal year 2013 budget proposal, also proposed shortening the market exclusivity period for biologics from twelve to seven years. (The foregoing, however, would
require a legislative solution.) The Office of Management and Budget estimates that reducing the exclusivity period for biological products that have lost patent protection would save $3.8 billion over 10 years. In addition, the Congressional Budget Office estimates that biosimilar prices would be about 40 percent lower than their brand-name counterparts.

AMA POLICY

Council on Medical Service Report 4-I-06, an informational report, outlined issues associated with tracking and analyzing specialty drug utilization data, examined the use of specialty pharmacies, and summarized new information about the use of drug formularies. Previously, CMS Report 2-I-05 highlighted trends associated with the availability, cost, and utilization of specialty drugs; examined the use of tiered formularies; and explored other alternatives for managing the high cost of specialty drugs. The resulting policy expressed support for complete transparency of health care coverage policies related to specialty drugs, including co-payment or co-insurance levels and how these levels are determined (AMA Policy H-185.953).

Regarding cost-sharing arrangements for prescription drugs in general, CMS Report 1-I-07 examined factors influencing prescription drug prices, and trends in prescription drug spending and insurance coverage of drugs; presented information regarding the use of co-payments and coinsurance; discussed value-based benefit design as an alternative to traditional benefit design; and described the ways in which increased price transparency can encourage efficient and appropriate use of prescription drugs. The report established Policy H-110.990, which has served as the foundation for AMA advocacy concerning patient cost-sharing for prescription drugs, and states that our AMA:

- Believes that cost-sharing arrangements for prescription drugs should be designed to encourage the judicious use of health care resources, rather than simply shifting costs to patients;
- Believes that cost-sharing requirements should be based on considerations such as: unit cost of medication; availability of therapeutic alternatives; medical condition being treated; personal income; and other factors known to affect patient compliance and health outcomes; and
- Supports the development and use of tools and technology that enable physicians and patients to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions, so that physicians and patients can work together to determine the most efficient and effective treatment for the patient’s medical condition.

As part of its policy foundation addressing the tiering of prescription drug cost-sharing, Policy H-125.991 supports mechanisms, such as incentive-based formularies with tiered co-pays, to allow greater choice and economic responsibility in drug selection, but urges managed care plans and other third party payers to not excessively shift costs to patients. Policy H-330.899 states that a drug benefit under Medicare should include a tiered deductible and co-payment structure that encourages economically responsible behavior. Policy D-110.992 states that the AMA will work with the insurance industry to ensure that patients with catastrophic diseases have an upper limit on copayments and deductibles sufficient to keep therapy affordable.

Policy H-155.960 supports the use of targeted benefit design by third-party payers, whereby patient cost-sharing requirements are reduced for maintenance medications used to treat chronic medical conditions, particularly when non-compliance poses a high risk of adverse clinical outcome and/or high medical costs. The policy notes that consideration should be given to tailoring cost-sharing


requirements to patient income and other factors known to impact compliance. The Council will be reviewing the subject of value-based insurance design for a report that will be presented at the 2013 Annual Meeting.

With respect to physician payment for biologics, CMS Report 3-I-08, which modified Policy D-330.960, described the coverage and payment of biologic and pharmacologic agents, reviewed the impact of the average sales price (ASP) payment system on physician practices, discussed the viability of the competitive acquisition program as an alternative to the ASP-based payment system, and identified trends in patient access to care. Policy D-330.960 states that our AMA will actively support 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 calls for the AMA to 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. Policy D-70.970 supports efforts to ensure that infusion supervision codes appropriately reflect the complexity of the infusion service rendered, and that there are sufficient relative value units to such service provided, as well as attendant practice expense, so that patient access to infusion therapies remains uninterrupted.

Policy H-373.998 supports patient choice of health plan, which includes prescription drug coverage. Policy H-165.839 states that health insurance exchanges should maximize health plan choice for individuals and families purchasing coverage, and that health plans participating in health insurance exchanges should provide an array of choices, in terms of benefits covered, cost-sharing levels, and other features. Policy H-165.846 recognizes the need to educate patients and assist them in making informed health plan choices, including ensuring transparency among all health plans regarding covered services, cost-sharing obligations, out-of-pocket limits and lifetime benefit caps, and excluded services.

DISCUSSION

While pharmacy benefit designs are often used with the goal of controlling the costs of prescription drugs, the Council believes that another key goal of pharmacy benefit designs should be to improve patient treatment and adherence. Adherence by patients to treatments involving specialty drugs is especially critical, as noncompliance with their treatment regimens can lead to worsening of symptoms or disease, hospitalizations and other costly interventions. The focus, therefore, should be on ensuring that patients can access and afford specialty drugs, as well as on the appropriate use of specialty drugs. The Council reiterates that comparative effectiveness research has the potential to play a key role in determining which specialty drugs work best for a subset of patients, helping to ensure that appropriate patients are being selected and have access to such treatments.

Cost-sharing for specialty drugs impacts patient use of and access to specialty drugs. Considering the medical conditions managed by specialty drugs and in the absence of therapeutic alternatives, pharmacy benefit designs that involve higher cost-sharing levels for specialty drugs compared with other drugs does not steer patients to more affordable alternatives. Instead, it transfers a larger financial burden to patients, who only have one treatment option for their medical conditions but may very well find the cost-sharing required for their needed specialty medication onerous and cost-prohibitive. Studies have shown that new users of specialty drugs are more sensitive to higher copayments than ongoing users, so that high levels of cost-sharing may have the effect of delaying or preventing patient access to needed treatments. Ongoing users may demonstrate cost-related non-adherence to specialty drugs by discontinuing the use of the specialty drugs.
The Council reiterates its commitment to achieve better value for health spending, and has previously defined value as the best balance between benefits and costs, and better value as improved clinical outcomes, quality, and/or patient satisfaction per dollar spent. The Council notes that pharmacy benefit designs have the potential to reduce value if they manipulate cost-sharing without regard for therapeutic value, possibly posing a financial burden on patients who need expensive but clinically effective specialty drugs. Instead, pharmacy benefit designs should prioritize value in health care spending. As such, the Council reiterates its support for targeted benefit design as outlined in Policy H-155.960, whereby patient cost-sharing requirements are reduced for maintenance medications used to treat chronic medical conditions, particularly when non-compliance poses a high risk of adverse clinical outcome and/or high medical costs. This policy also recognizes that consideration should be given to tailoring cost-sharing requirements to patient income and other factors known to impact compliance. The Council notes specialty drugs are particularly suited to targeted benefit design, which would promote the efficient and effective use of specialty drugs.

Overall, the Council believes that Policy H-110.990 outlines a sound approach to appropriate cost-sharing for specialty drugs. The purpose of cost-sharing for prescription drugs in general should be to encourage the judicious use of health care resources, rather than simply shifting costs to patients. The Council also views income-based pharmacy benefit design as an emerging trend, and believes that this design strategy is supported by Policy H-110.990[2] that states that cost-sharing requirements should be based on considerations including personal income. Increased adoption of income-based benefit design has the potential to reveal its success in ensuring the affordability of and compliance with specialty drugs, as well as its prospects for long-term financial stability and sustainability as a benefit design option.

Policy H-110.990[3] underlines the importance of physicians and patients being able to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions, so that physicians and patients can work together to determine the most efficient and effective treatment for the patient’s medical condition. However, the Council notes that a need also exists to educate patients and assist them in making choices during their health plan selection, as outlined in Policy H-165.846, which highlights the need for transparency regarding covered services, cost-sharing obligations, out-of-pocket limits and lifetime benefit caps, and excluded services. Patient awareness of out-of-pocket limits of health plans in this arena is essential, as in most cases, health plans cover all of the costs they consider to be medically necessary beyond the out-of-pocket maximum. As a result, with such transparency, patients will have the ability to select a plan that meets their health care needs and is affordable.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 802-I-11 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-155.960, which supports the use of targeted benefit design as a strategy to address rising health care costs. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy H-110.990, which stresses that cost-sharing arrangements for prescription drugs should be encourage the judicious use of health care resources, rather than simply shift costs to patients. (Reaffirm HOD Policy)
3. That our AMA reaffirm Policy H-165.846, which stresses the importance of health plan transparency and patient education and assistance in health plan selection. (Reaffirm HOD Policy)

Fiscal Note: Less than $500.

References are available from the AMA Division of Socioeconomic Policy Development.