The following report was presented by James G. Hinsdale, MD, Chair, Council on Medical Service; and Robyn F. Chatman, MD, MPH, Chair, Council on Science and Public Health:

1. ALIGNING CLINICAL AND FINANCIAL INCENTIVES FOR HIGH-VALUE CARE

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION: RECOMMENDATIONS ADOPTED

REMAINDER OF REPORT FILED

See Policy D-185.979

The Council on Medical Service and the Council on Science and Public Health present this joint report to expand upon prior studies of access to and coverage for preventive services and other high-value health care services. The Councils decided to pursue this report in light of: (a) the confusion among provider, patient, and payer communities in paying for preventive services; and (b) a common goal of improving affordable access to “high-value” services (as described below).

One factor mitigating patient concerns about the cost of preventive care is the Affordable Care Act’s (ACA) requirement that health plans cover select preventive services without any patient cost-sharing (zero-dollar). The Councils previously considered preventive services in the Council on Medical Service and Council on Science and Public Health Joint Report at the 2017 Annual Meeting, “Value of Preventive Services.” As detailed in the A-17 report, the ACA required all private, non-grandfathered health insurance plans to provide zero-dollar coverage for the preventive services recommended by four expert organizations: the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the Women’s Preventive Services Initiative, and Bright Futures. The report also described the varied methods used by those four organizations for developing preventive service guidelines. The report established Policy H-460.894, which encouraged those organizations to develop their recommendations with transparency, clarity and specificity. Given the significant challenges that have arisen as the health care industry strives to provide zero-dollar coverage for the expert organizations’ recommendations, further study was warranted to explore additional policy options for promoting access to preventive interventions.

The ACA requirement of coverage for select preventive services without cost-sharing has been a popular and successful step in promoting access to preventive care, but more could and should be done to facilitate and incentivize high-value care. Value-Based Insurance Design (VBID) is a potential partial solution consistent with long-standing American Medical Association (AMA) policy. This report highlights the utilization of preventive services under ACA’s mandated zero-dollar coverage, key challenges posed by the ACA-mandated coverage, legal and regulatory obstacles, examples of how VBID has been used successfully to better align incentives for high-value care, and opportunities for expanded use of VBID. Finally, this report makes several policy recommendations.

BACKGROUND

Health care affordability is determined not just by the cost of insurance coverage (e.g., the premium), but also by the amount of cost-sharing required (e.g., deductibles, co-payments, and coinsurance). The median level of liquid assets among nonelderly American households was below the cost-sharing requirements of many health insurance plans and significantly below the maximum out-of-pocket limits allowed for private insurance in 2016, indicating potential challenges, especially for families with low incomes and/or significant medical bills.

Concerns about the cost of care have caused some Americans to delay or skip necessary health care. In a recent poll (n=1,302), more than a third of Americans indicated that they made health care decisions in the past year based on costs, including 44 percent who reported not going to the doctor when they were sick or injured, 40 percent who reported going without a routine physical or other preventive care, 40 percent who reported skipping a medical test or treatment, and 32 percent who reported either not filling a prescription or taking less than the prescribed dose.

Patients and physicians alike encounter a dilemma when an ACA-designated preventive service that is provided without patient cost-sharing identifies early stage illness, and subsequent medical interventions can impose significant

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out-of-pocket costs on patients. At the same time, such interventions can be characterized as “high-value” care—they potentially minimize human suffering, maximize the opportunity for beneficial medical intervention, save the health care system the costs of treating advanced disease, and save society the costs of losing productive individuals. Inherently, “high-value” care is subjective and challenging to define—the same service can be life-saving for one patient and over-treatment for another patient. Accordingly, rather than restricting “high-value” care with one specific definition, experts explain that the key is for the health care system to embrace the concept that not all care provides equal value. It is not necessary for all to agree which services must always be considered “high-value.” Instead, simply building consensus around some selected services and aligning payer, provider, and patient incentives around those services is beneficial. This report explores opportunities to identify high-value care, some of the ways in which incentives are currently misaligned, methods already being used successfully to promote more optimal alignment, and policy recommendations to advance progress in this space.

SUCSESSES AND CHALLENGES IN IMPLEMENTING THE ACA PREVENTIVE SERVICES BENEFITS

The ACA’s mandated zero-dollar coverage for select preventive services enjoys strong bipartisan support. A recent poll found that the ACA provision eliminating out-of-pocket costs for certain preventive services was favored by 83 percent of Americans (n=1,202) surveyed, including 89 percent of Democrats, 83 percent of Independents, and 77 percent of Republicans. Prior to the ACA it was estimated that Americans received only about half of the preventive services that are recommended. While it is estimated that 71 million Americans received expanded coverage of one or more preventive services in 2011 and 2012 as a result of the ACA, studies examining the utilization of preventive services over a limited time horizon post-ACA have found mixed results. For example, among adults (age 18 to 64), the ACA was associated with an increase in physicians’ provision of preventive cardiovascular services, including the use of diabetes screening, tobacco use screening, hypertension screening, and aspirin therapy in men. It was also associated with increases in up-to-date rates of routine checkups and flu vaccinations. However, changes in blood pressure checks, cholesterol checks, and certain cancer screenings were not associated with the ACA. A review of studies focused on the ACA’s impact on cancer screening found mixed results. While studies indicated that some cancer screening (pap smear test, mammography, and colorectal cancer screening) did not increase post-ACA implementation, other studies found statistically significant increases in earlier diagnosis of certain cancers associated with Medicaid expansion and parents’ ability to maintain insurance coverage for their children up to age 26. Multiple studies also have found evidence of substantial positive impacts among low-socioeconomic status groups and groups subject to high cost-sharing prior to the ACA. While such initial studies are informative, additional research across longer time horizons is necessary to fully understand the impact of the ACA benefit that removed cost-sharing for select preventive services on utilization and health outcomes.

Similarly, even with cost-sharing barriers removed, additional barriers to provision of preventive services still exist and may include inconsistently applied definitions of key terminology, limited knowledge of preventive service guidelines, and limited time with patients. For example, the classification of a service as “screening,” “diagnostic,” or “therapeutic” can be unclear. Some of this confusion can be traced back to legal definitions of “preventive care.” As explored in greater detail above, preventive care takes on legal significance in the context of health savings accounts (HSAs) associated with eligible high deductible health plans (HDHPs), as these plans generally cannot cover medical items or services until the deductible is met. A preventive care safe harbor via Section 223(c)(2)(C) of the Internal Revenue Code provides an exception to this rule for certain preventive care. However, preventive care is not clearly defined by law. Given the significant inconsistency and confusion that persists when referring to preventive services, this report will avoid use of the commonly confused terms. Additionally, patients are not familiar with the preventive services that are available to them without cost-sharing. Three and half years after the ACA took effect, less than half the population (43 percent) reported being aware that the ACA eliminated out-of-pocket expenses for preventive services.

Underinsurance & Cost-Related Non-Adherence (CRN): While increasing access to health insurance has been beneficial to patients, it is nevertheless critical to recognize the challenges posed by underinsurance and CRN. Rates of underinsurance—defined as out-of-pocket costs that are high relative to income—have risen, with 13 percent of adults underinsured in 2005, and 28 percent of adults underinsured in 2016. Even when a service is covered by a health plan, patients may incur significant costs in the form of co-payments, coinsurance, and/or large medical bills that they must pay before meeting their deductible. Such costs have been shown to cause people, especially those in low-income and vulnerable populations, to forgo not only unnecessary but also necessary care. In fact, as little as a $10 rise in co-payments has been associated with a significant decline in outpatient visits and a concurrent increase in hospital utilization among an elderly population. Similarly, CRN refers to a state in which patients are unable to
pursue recommended medical care due to financial barriers. Sub-optimal use of evidence-based medical services can lead to negative clinical outcomes, increased disparities, and in some cases, higher aggregate costs. CRN has been identified across the entire continuum of clinical care—physician visits, preventive screenings, prescription drugs, etc.—and it is especially problematic for vulnerable populations, such as those with multiple chronic conditions, and for socioeconomically and racially disparate populations. For example, greater out-of-pocket costs for medication to treat certain chronic conditions has been found to reduce initiation and adherence, lower the likelihood of achieving desired health outcomes, and sometimes, increase utilization of acute care services. At the same time, studies have demonstrated that reducing or eliminating cost-sharing leads to improvements in medication adherence and reductions in socioeconomic and racial disparities.

Both underinsurance and CRN can be exacerbated in the context of the rising prevalence of HDHPs. HDHPs are insurance plans associated with lower premiums, higher deductibles and greater cost-sharing requirements as compared with traditional health plans. An HDHP is frequently combined with a personal health account, a combination referred to as a “consumer-directed health plan.” A personal health account can either be a HSA or health reimbursement arrangement (also known as a health reimbursement account or HRA). HSAs are tax-free accounts used to pay for qualified medical expenses, and they must be paired with an HDHP. HRAs are employer-funded accounts used to reimburse employees for qualified medical expenses. HRAs need not be paired with an HDHP. While employees can keep unspent money in an HSA and accumulate savings from year to year, unspent HRA funds are forfeited to the employer at the end of a calendar or benefit year. Enrollment in HDHPs by individuals younger than 65 years who have private health insurance has increased sharply—from 25.3 percent of the population studied in 2010, to 47.0 percent in the first three months of 2018. Moreover, the size of deductibles has increased dramatically. In 2003, only one percent of adults enrolled in a private plan had a deductible of $3,000 or more, but by 2016, that percentage rose to 13. HDHPs appear to reduce health care costs by decreasing the use of both appropriate care (such as recommended cancer screenings) and inappropriate care (such as low-severity emergency department visits). Greater consumer cost-sharing is frequently used as a lever to minimize the growth of health insurance premiums. Studies have found that families who have members with chronic disease and who are enrolled in HDHPs are more likely to go without care due to cost and/or face substantial financial burdens, such as trouble paying bills, than families enrolled in traditional plans. Another study found that enrollment in an HDHP, combined with an HRA or HSA, led to significant increases in out-of-pocket spending, with more than half of the enrollees with lower-incomes and more than one-third of the enrollees with chronic conditions facing “excessive financial burden.”

At the same time, patients’ deductibles are only a fraction of their total out-of-pocket spending. Once coinsurance and co-payments are also factored in, a recent study of individuals enrolled in large employer health plans (n=between 1.05 and 15.3 million per year) found that total out-of-pocket spending rose by 54 percent between 2006 and 2016, from an average of $525 in 2006 to an average of $808 in 2016. Moreover, individuals in the top 15 percent of health spenders (who account for 79 percent of total health spending), had out-of-pocket costs averaging $2,837 in 2016. Exacerbating this challenge is the fact that while out-of-pocket health care costs have been rising in recent years, wages have been relatively stagnant.

In light of these significant financial concerns, it is especially important that patients understand the availability of certain preventive services without any cost-sharing. Moreover, as described later in this report, efforts are underway to remove legislative and regulatory barriers to innovative insurance plan designs that could better align incentives around high-value services.

Coding, Billing, and Payment Challenges: The mismatch between the clinical intent of expert organizations’ evidence-based recommendations and the ACA’s mandated insurance coverage of recommended preventive services has added complexity to billing and payment practices, sometimes resulting in unexpected, and perhaps unintended, patient cost-sharing. Some specific challenges include:

- When a patient receives a designated preventive service, a private health insurance plan may still impose cost-sharing if: (1) the provider bills the services and the visit separately; or (2) the preventive service was not the primary purpose of the visit. Moreover, guidance is not clear regarding who determines what constitutes the primary purpose of a visit.
- If the expert organization does not specify the “frequency, method, treatment or setting” for a service, private health plans may use “reasonable medical management techniques” and “the relevant evidence base” to shape coverage/coverage limitations.
A private health plan may impose cost-sharing for treatment that is needed subsequent to a designated preventive service.

Certain USPSTF recommendations apply only to “average risk” or certain “high-risk” populations. As a result, only those patients are entitled to receive the preventive service without cost-sharing. Federal guidance has clarified that the designation of “high-risk” is left to the attending provider. However, it can be unclear how a health plan is to know when a service was provided to a patient who is entitled to the service at no cost-share. Current Procedural Terminology (CPT) modifier 33 can be used when billing for ACA-designated preventive services. The addition of modifier 33 communicates to a commercial payer that a given service was provided as an ACA preventive service. While modifier 33 does not apply to Medicare patients, the CPT modifier was developed to indicate that a colonoscopy that was scheduled as a screening was converted into a diagnostic or therapeutic procedure. Nevertheless, review of the literature indicates that confusion and inconsistency persist among providers and payers in coding and paying these claims and may be contributing to the misaligned expectations observed throughout the health care industry.

It is unclear what state and federal systems are in place to monitor and ensure enforcement of the ACA requirements. Even if individuals know they are entitled to receive certain preventive services without cost-sharing, they may not know how to seek redress if they are charged for these services.

EXPANDING ACCESS TO HIGH-VALUE SERVICES

In addition to the implementation challenges described above, patients and physicians find themselves challenged when findings from a zero-dollar preventive service lead to very expensive subsequent medical care. Furthermore, preventive interventions not designated by ACA that are deployed to prevent significant morbidity may be associated with significant patient cost-sharing. Accordingly, health plan financial incentives for patients do not always support the goal of proactively managing medical risk and preventing serious morbidity.

The juxtaposition of legitimate patient financial concerns and the high value of many preventive interventions highlights significant misalignment of clinical and financial incentives that pervades our health care system. While designation by expert organizations of preventive services to be provided without cost-sharing is a start, an initial designated service may be insufficient to achieve broader clinical goals. Instead, subsequent necessary steps can require significant financial outlays by the patient. In these cases, the clinical impact of a recommended service may not fulfill its potential if patients are unable to follow through on their physicians’ guidance due to financial barriers. Several of the current system’s misaligned incentives are illustrated below.

Misaligned Incentives – More Invasive Services: For clinical and economic reasons, it can make sense to promote less expensive, less-invasive screening as a first step, and progress to invasive tests when medically indicated. However, the current system sometimes incentivizes the opposite, when lower cost-sharing levels sometimes apply to more expensive, more invasive procedures. For example, consider a primary care physician who wants to follow the USPSTF’s recommendation and encourage a 55 year-old patient to receive colorectal cancer screening. The physician discusses the recommendation with the patient, and the patient refuses to receive a colonoscopy (citing fear of the bowel preparation, fear of anesthesia, etc.). The physician and the patient agree that for this patient, Cologuard®, a non-invasive stool test, is an appropriate initial method of screening. The Cologuard® is provided to the patient without cost-sharing. However, when the results of the Cologuard® are positive, the physician advises that a colonoscopy is necessary to complete the colorectal cancer screening. While this colonoscopy would have been provided without cost-sharing had it been chosen as the first screening method, a colonoscopy that follows a positive stool test sometimes results in imposition of a significant cost-sharing burden on the patient. The potential cost burden, in addition to the patient’s already established concerns regarding colonoscopy, may dissuade the patient from completing the screening process.

Misaligned Incentives – Individual Risk Factors: In striving to prevent advanced disease, physicians often identify individual risk factors that subject their patients to a greater than average risk of various diseases. Some may be at higher risk for breast cancer, and others at higher risk for diabetes, and some may be at heightened risk for multiple serious diseases. Ideally, financial incentives would encourage patients to receive high-value services that are most likely to help them as individuals, and prioritize those over services that are less aligned with their individual risk profile. However, under our current health care system, individuals at heightened risk can be precluded from cost-sharing incentives for some high-value services.
For example, the USPSTF recommends breast cancer screening mammography for asymptomatic women who are not at high risk for breast cancer. Women at high risk include those who have preexisting breast cancer, a previously diagnosed high risk breast lesion, a known underlying genetic mutation (such as a BRCA1 or BRCA2 gene mutation or other familial breast cancer syndrome), or a history of chest radiation at a young age. A biannual mammogram will be free of cost-sharing to a woman at average risk. However, women who are at heightened risk, who need the test most frequently, and for whom the test may more often be positive, must share in often significant costs. While screening mammography is not provided without cost-sharing to patients at increased risk for breast cancer, the USPSTF recommends that “for women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene.” Thus, a patient at increased risk for breast cancer may receive risk-reducing medications without cost-sharing, but must share in the costs of mammography.

Misaligned Incentives – Detection vs. Monitoring, Treatment, and Continuing Prevention: When physicians choose to screen their patients for a given disease, their goal is not to simply provide a diagnosis, but rather to help their patients manage risk and promote long-term health. Under our current health care system, risk can be identified without cost-sharing, but the management of that risk can burden patients with significant financial costs.

For example, the USPSTF recommends that fair skinned young adults, adolescents, children, and parents of young children receive counseling regarding minimizing exposure to ultraviolet radiation to reduce their risk of skin cancer. Counseling would be covered without patient cost-sharing. However, consider a situation where the counseling primary care physician refers a fair skinned young adult to a dermatologist for a visual skin examination. A visual skin exam by a dermatologist may help prevent or detect skin cancer. However, the USPSTF concluded that the current evidence is insufficient to assess the balance of benefits and harms of visual skin examinations by clinicians and whether such exams reduce skin cancer-related morbidity and mortality. A visual skin exam conducted by a dermatologist would likely result in patient cost-sharing, which may be significant, especially if the patient has not yet met their plan deductible. If the dermatologist decides to biopsy a mole, the procedure and pathology may incur significant cost-sharing for the patient. If the biopsy indicates early stage malignancy, removing the mole may prevent serious morbidity, but it may result in substantial additional cost-sharing. Finally, to ensure that subsequent disease is prevented and/or eradicated before it becomes invasive, a treating physician would want to incentivize this patient to practice on-going preventive habits such as purchasing and utilizing sunscreen and committing to follow-up visits with a dermatologist. However, since the purchase of sunscreen and dermatologist visits are outside the scope of the USPSTF, these valuable items and services will impose significant lifetime costs on the patient.

One can anticipate how similar misaligned incentives pervade our current system, in attempts to prevent morbidity from cancer, mental illness, and many other chronic diseases. For example, the USPSTF recommends screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese. Moreover, the USPSTF encourages clinicians to offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity. However, an array of evidence-based services to prevent onset of diabetes (e.g., community health worker diabetes prevention programs (DPPs) and combined diet and physical activity promotion programs) and/or to prevent disease advancement and morbidity (e.g., insulin to keep blood glucose well-managed, regular eye and foot examinations, etc.) are outside the scope of the ACA’s mandated zero-dollar benefit and subject to significant patient cost-sharing. While studies have found savings of approximately $1,300 for every Medicare Advantage (MA) patient who completed a diabetes education program, insured patients may, due to cost-sharing, expend hundreds of dollars to participate. Consider this in the context of the finding, described above, that even a $10 increase in co-payments has been associated with a significant decline in outpatient visits and a concurrent increase in hospital utilization among an elderly population. Recognizing the value of prevention programs, some payers interpret the USPSTF recommendation broadly and/or develop a commitment to covering DPPs as an evidence-based preventive program that mitigates rising risk. Such payers, including commercial health plans, as well as some Medicare and Medicaid programs, offer DPPs as a preventive service without patient cost-sharing.

An additional facet of misaligned incentives arises when patients find themselves “penalized in the form of high cost-sharing simply because of their biology.” For example, consider patients with major depressive disorder. Some patients may respond well to generic medications that are subject to the lowest level of cost-sharing. Other patients, though, may not achieve the desired clinical outcome with the less expensive medication, and to prevent disease progression, those patients may require medication that is only available at a higher level of cost-sharing. This higher level of cost-sharing, however, can disincentivize medication initiation and adherence.
Accordingly, in considering actions that can be taken to improve access to high-value care, it is imperative to look at Value-Based Insurance Design (VBID): Health plans can apply VBID principles to design benefits that reduce cost-sharing and encourage the use of high-value care. VBID plans use cost-sharing as a tool to provide incentives and reduce costs. In contrast, traditional health insurance plans may impose significant cost-sharing for specialist visits and diabetes prevention programs (DPP). However, if the patients’ insurance benefits impose significant cost-sharing for specialist visits and/or DPP enrollment, the patients may not have the financial means to follow through with their primary care physicians’ advice. As a result of these misaligned incentives, the system may face: (a) primary care physicians who cannot meet their quality metrics due to patient non-compliance; (b) patients who forgo high-value care due to financial barriers and subsequently become sicker; (c) employers that lose productivity due to employee illness; and (d) payers that ultimately pay more money to care for sicker patients. Clearly, this is an avoidable result that benefits no one.

Value-Based Insurance Design (VBID): Health plans can apply VBID principles to design benefits that reduce financial barriers to and incentivize the use of high-value care. VBID was designated as a federal policy priority in the ACA, and the AMA has long supported VBID, with the Council on Medical Service issuing a report at the 2013 Annual Meeting that set forth principles to guide implementation of VBID initiatives. As explained in CMS Report 2-A-13, traditional health insurance benefit designs use patient cost-sharing primarily as a way to control health care costs. In contrast, VBID uses cost-sharing as a tool to encourage the use of specific health care services based on “value,” which is defined as the clinical benefit gained for the money spent. While traditional benefit designs apply a standard set of cost-sharing requirements to all services and all patients, VBID determines coverage and cost-sharing rules based on an assessment of the clinical value of individual health care treatments or services. VBID plans vary patients’ out-of-pocket costs, such as co-payments, coinsurance, and deductibles, based on the value of specific services. Specifically, VBID plans are designed in accordance with the tenets of “clinical nuance,” recognizing that (1) medical services may differ in the amount of health produced; and (2) the clinical benefit derived from a specific service depends on the person receiving it, as well as when, where, and by whom the service is provided.
Applying “clinical nuance,” health plans can address some of the misaligned incentives. Returning to the example of a patient with uncontrolled blood glucose introduced above, to prevent complications associated with diabetes, and to incentivize adherence to evidence-based measures, a VBID plan may choose to reduce the cost-sharing associated with critical diabetes items or services such as insulin therapy or vision exams. VBID principles can be applied to prescription drug formularies according to a “reward the good soldier” or “step edit with co-pay relief” strategy. Under such models, if a patient tries a first-line lower-cost therapy, and that therapy proves to be ineffective in achieving the desired clinical outcome for that patient, the patient would be able to access an otherwise more expensive therapy at a lower cost-sharing level. A recent systematic literature review found that using a VBID approach to decreasing cost-sharing for targeted prescription drug classes was significantly associated with improved medication adherence, and limited evidence also indicated improvement in clinical outcomes and quality. Moreover, there was no effect on total health care spending, suggesting that the increased spending on prescription medication was offset by decreased spending on other medical items or services.

**VBID Program Expansion:** Currently, hundreds of private self-insured employers, public organizations, nonprofits and insurance plans have designed and tested VBID programs, and VBID experts believe the design method has reached a “tipping point.” The recently enacted Bipartisan Budget Act of 2018 incorporates the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017 and requires expansion of the Medicare Advantage Value-Based Insurance Design Model to all 50 states by no later than January 1, 2020. The model allows MA plans the flexibility to reduce cost-sharing or offer supplemental benefits to enrollees with specified chronic conditions, focusing on the services that are of highest clinical value to them.

In addition to the **MA VBID model**, the federal government continues to embrace VBID by supporting expanded application of VBID principles by public and private payers. The Centers for Medicare & Medicaid Services MA Final Rule for contract year 2019 provides greater flexibility around the MA uniformity requirement to allow for the implementation of VBID principles throughout the MA program. This flexibility gives MA plans new tools to improve care and outcomes for enrollees by allowing MA plans to reduce cost-sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer different deductibles for beneficiaries who meet specific medical criteria. TRICARE is also working to improve health outcomes and enhance the experience of care for US Armed Forces military personnel, military retirees, and their dependents through VBID pilot programs. The 2017 National Defense Authorization Act (NDAA) commissioned a pilot program to demonstrate and test the feasibility of incorporating VBID into the TRICARE program, and the 2018 NDAA further incorporates VBID principles into the TRICARE Pharmacy Benefits Program.

Connecticut implemented a collectively bargained state-based VBID program for its state employees that is one of the first to apply VBID to not only prescription drugs, but to reduce cost-sharing for enrollees across the spectrum of care, including medical services for chronic diseases. Moreover, this Connecticut program both removed financial barriers to services known to be clinically valuable and instituted requirements that enrollees obtain certain preventive services, with the goal of encouraging enrollees to participate in their preventive and chronic disease care. Connecticut implemented its program in 2011, and early results were published in 2016. While more research is needed to inform optimal design of VBID plans, early evidence is encouraging. Highlights of the Connecticut model include:

- Enrollees overwhelmingly chose to enter and stay in the VBID plan. While participation in the plan was voluntary, first year enrollment exceeded 98 percent and about 98 percent of the enrollees were deemed compliant with the plan requirements at the end of each of the first two years of the program.
- There were significant gains in preventive office visits and nearly all of the targeted preventive screenings in both the first and second years of the program.
- The total number of emergency department visits without a resulting hospital admission decreased significantly in both the first and second years of the program.
- For the chronic diseases studied, there were significant increases in physician office visits and medication possession ratios, relative to a comparison group.

Connecticut’s experience suggests that payers considering VBID programs should proactively weigh the benefits of potentially improved health and productivity against the potential for higher costs that can be associated with increased use of high-value services. Connecticut’s program also highlights critically intertwined drivers of health care spending: (a) the majority of overall health care spending is dedicated to chronic disease; (b) most chronic diseases have evidence-based quality metrics; (c) evidence indicates suboptimal performance on those quality metrics; and
(d) patient out-of-pocket spending is a significant contributor to underutilization of care. Other payers could replicate the Connecticut plan’s focus on chronic conditions.\textsuperscript{76}

Centers for Disease Control and Prevention (CDC) 6|18 Initiative: The CDC’s 6|18 initiative is another example of efforts underway to align purchasers, payers, and providers to improve health and control costs through increased coverage of evidence-based preventive interventions. The initiative focuses on preventing chronic and infectious disease by increasing coverage, access, utilization, and quality. The CDC is specifically targeting six common and costly health conditions – tobacco use, high blood pressure, health care-associated infections, asthma, unintended pregnancies, and diabetes.\textsuperscript{77} Eighteen evidence-based-interventions have been identified as a starting point of discussions with purchasers, payers, and providers.\textsuperscript{78} The CDC is providing technical assistance to state Medicaid programs and public health departments to implement the prioritized interventions and to private payers to help them identify interventions that will help their beneficiaries.

Barriers to VBID Expansion: Obstacles will likely prevent optimal customization of VBID plans in the short-term, as there are significant administrative burdens associated with identifying which services are highest value for which plan beneficiaries. However, plans should be encouraged to experiment with innovative plan designs that implement discrete elements of VBID, and legislative and regulatory changes would facilitate this goal.

HSA-HDHPs are among the fastest-growing plan types in the United States, and while current Internal Revenue Service (IRS) regulations permit a “safe harbor” that allows for coverage of specified preventive services prior to satisfaction of the plan deductible, that safe harbor is significantly limited.\textsuperscript{79} IRS regulations state that clinical services meant to treat “an existing illness, injury, or condition” cannot be included in pre-deductible coverage.\textsuperscript{80} Thus, even if a health plan would like to develop an HSA-HDHP according to VBID principles, many essential clinical services used to manage chronic illness could not be covered in HSA-HDHPs before the entire deductible is met. However, when HSA-HDHP enrollees with existing conditions or risk factors are required to pay out-of-pocket for necessary services prior to meeting the plan deductible, the results can be lower utilization of care, potentially resulting in poorer health outcomes and higher costs.\textsuperscript{81}

VBID experts refer to a natural evolution from the current HSA-HDHP system to a “High-Value Health Plan” (HVHP) system that grants insurers the flexibility to provide pre-deductible coverage for high-value services across the spectrum of clinical care.\textsuperscript{82} Legislative and regulatory barriers should not prevent this evolution, and bipartisan efforts are underway to remove these barriers. The bipartisan, bicameral “Chronic Disease Management Act of 2018” (S.2410, H.R.4978) was introduced in February 2018, and if enacted, would permit HDHPs “to provide chronic disease prevention services to plan enrollees prior to satisfying their plan deductible.”\textsuperscript{83} VBID experts explain that this strategy would lower US health care expenditures and provide millions of Americans expanded plan options that better meet their clinical needs and contribute to their financial well-being.\textsuperscript{84} America’s Health Insurance Plans has also explained that this approach would improve the value of HSA-qualified plans for consumers and improve access to care for chronic conditions.\textsuperscript{85}

While VBID is not a panacea to singlehandedly expand access to and utilization of all critical high-value preventive interventions, it is a powerful tool. Other tools include literacy programs, health-information technology interventions and alternative clinician payment models,\textsuperscript{86} all of which are consistent with AMA policy.

AMA POLICY

The AMA has extensive policy supporting evidence-based preventive services. Policy H-165.840 advocates for evidence-based prevention to be covered for all patients. Policy H-425.997 supports coverage for evidence-based, cost-effective preventive services; Policy H-165.848 supports a requirement that preventive health care be included as minimal coverage and Policy H-390.849 supports providing patients with information and incentives to encourage appropriate utilization of preventive services. Regarding alignment of covered benefits, Policy H-425.994 emphasizes the importance of only pursuing testing in patients when adequate treatment and follow-up can be arranged for identified abnormal conditions and risk factors and Policy D-385.966 encourages reasonable payment for mandated benefits in health insurance policies. Additionally, Policy H-165.846 sets forth principles to guide the evaluation of the adequacy of health insurance coverage options.

Moreover, Policy H-425.986 encourages communication and cooperation among physicians and public health agencies to address challenges in preventive medicine. Policies D-330.967 and H-425.987 support continued
collaboration with national medical specialty societies and interest groups to encourage coverage for evidence-based recommendations regarding preventive services, especially for populations at high risk for a given condition. Policy H-440.875 emphasizes the AMA’s commitment to collaborating to assure access to ACIP-recommended vaccines. Policy H-425.988 supports continuing collaboration with the federal government, specialty societies, and others, to develop guidelines for, and effective means of delivery of, clinical preventive services. Similarly, Policy D-330.935 states that the AMA will collaborate with relevant stakeholders, including appropriate medical specialty societies, to actively promote to the public and the profession the value of Medicare-covered preventive services and support the expansion of first-dollar coverage for a preventive visit and required tests anytime within the first year of enrollment in Medicare Part B. Policy H-425.992 advocates for revision of current Medicare guidelines to include coverage of appropriate preventive medical services.

Various AMA policies call for coverage with no cost-sharing, including: Policy H-185.969 regarding immunizations, Policy D-330.935 regarding Medicare preventive service benefits, and Policy H-290.972 for preventive coverage for HSA holders in the Medicaid program. Policy D-425.992 expresses concern regarding the effect that USPSTF recommendations can have on limiting access to preventive care for Americans (e.g., regarding access to screening mammography and prostate specific antigen screening) and encourages the USPSTF to implement procedures that allow for meaningful input on recommendation development from specialists and stakeholders in the topic area under study.

Finally, AMA policy strongly supports APMs, VBID, and innovative insurance design. Policy H-385.913 sets forth principles to guide physician-focused APMs. Policy H-450.938 has principles to guide physician value-based decision-making and emphasizes that physicians should seek opportunities to integrate prevention services into office visits. Policy H-155.960 supports value-based decision-making and reducing the burden of preventable disease as broad strategies for addressing rising health care costs. Moreover, this policy recognizes the role of physician leadership and collaboration among physicians, patients, insurers, employers, unions, and government in successful cost-containment and quality-improvement initiatives. The policy encourages third-party payers to use targeted benefit design, whereby patient cost-sharing is determined based on the clinical value of a health care service or treatment, with consideration given to further tailoring cost-sharing to patient income and other factors known to impact compliance. Policy H-185.939 broadly supports flexibility in the design and implementation of VBID programs and outlines a series of guiding principles including that VBID explicitly consider the clinical benefit of a given service or treatment when determining cost-sharing or other benefit design elements. Consistent with calls to remove legislative and regulatory barriers to innovation in HSA-HDHP plan design, Policy H-165.856 states that the regulatory environment should enable rather than impede private market innovation in product development and purchasing arrangements. At the same time, Policy H-165.856 states that benefit mandates should be minimized to allow markets to determine benefit packages and permit a wide choice of coverage options.

AMA ACTIVITY

In addition to the substantial volume of related AMA policy, AMA activities regarding high-value services have included:

- Serving as a liaison to expert organizations including the USPSTF, the ACIP, and Bright Futures.
- At the 2018 Annual Meeting, Policy H-185.960 was modified to specify that the AMA will develop a coding guide regarding colorectal cancer screening services to promote common understanding among health care providers, payers, health care information technology vendors, and patients.
- At the 2018 Annual Meeting, Resolution 226-A-18 regarding routine preventive prostate cancer screening was referred, and the Council on Medical Service is preparing a report for the 2019 Annual Meeting.
- As part of its strategic focus on improving health outcomes, the AMA has partnered with the CDC and DPPs to prevent type 2 diabetes and supports key legislation to prevent type 2 diabetes and improve care for current patients. As part of these efforts, the AMA has also urged both private and public health care payers to offer DPPs under their health plans to give more people access to these proven programs.87
- To address significant barriers to colorectal cancer screening for the Medicare population, AMA advocacy efforts supported requiring Medicare to waive the coinsurance for colorectal screening tests, regardless of whether therapeutic intervention is required during the procedure.
- Various AMA advocacy efforts have supported expansion of the MA VBID Model, including support for flexibility in MA uniformity (which would allow plan sponsors to target enhanced benefit design to certain
patients) and support for the Bipartisan Budget Act of 2018 (which incorporates the CHRONIC Care Act of 2017, which includes expansion of the MA VBID Model to all 50 states).

- In July 2018, the AMA sent a letter to Chairman Kevin Brady and Ranking Member Richard Neal of the House of Representatives Committee on Ways and Means supporting H.R. 6301, “to amend the Internal Revenue Code of 1986 to provide high deductible health plans with first dollar coverage flexibility.” H.R. 6301 would expand the access and enhance the utility of HSAs by offering health plans some flexibility in their plan design while still maintaining eligibility for HSA contributions.

- To help AMA members better understand the USPSTF’s methods for making evidence-based recommendations on clinical preventive services and how VBID can be used to expand affordable access to high-value services, the AMA held a continuing medical education session at the 2018 Annual Meeting.

DISCUSSION

Stakeholders throughout the health care community—providers, payers, community health professionals, and patients—can benefit from common understanding of which preventive services are covered without patient cost-sharing, and how such services should be coded. Moreover, stakeholders throughout the health care community should contribute to patient education regarding both the health care and economic value of zero-dollar preventive services so that patients can make well-informed decisions about their care. Physicians must be well-aware of recommended services available without cost-sharing so that they can have optimally productive consultations with their patients. The fact that these services are evidence-based and available at no cost to the patient may help physicians communicate the value of these services and help patients understand that cost should not be a barrier to this care. At the same time, proactive conversations between physicians and their patients about how a zero-dollar preventive service can lead to additional items or services that will incur cost-sharing will foster trust and understanding, and avoid unexpected medical bills. Additionally, public health organizations and payers (eg, employers and health plans) should be encouraged to educate the public/their members about recommended preventive services and their availability without cost-sharing. Such educational initiatives will empower patients to have productive conversations with their physicians about whether these services are appropriate for them.

The AMA can play a critical leadership role in building needed common understanding. The AMA, as the authority on CPT, is in a unique position to issue educational materials that can be seen as a source of truth in aligning recommended preventive services with the proper CPT codes for billing. Accordingly, the Councils recommend that the AMA develop coding guidance to help physicians correctly bill, and help payers correctly pay for, recommended preventive services. Additionally, the Councils recommend that the AMA develop physician education tools that help physicians prepare for conversations with their patients about the scope of preventive services provided without cost-sharing. This physician education can be designed to address two needs. First, these educational tools can address underutilization of zero-dollar preventive services by helping physicians communicate the clinical and financial value of these services to their patients. Second, these educational tools can address the patient experience of unexpected medical bills by preparing physicians (and their staff) to have proactive conversations about what is and is not provided within the scope of zero-dollar preventive services.

The USPSTF and the other ACA-designated expert organizations cannot reasonably be expected to develop recommendations on every risk-reducing course of action for every disease. At the same time, it is difficult to rationalize why some individuals at heightened risk for some diseases receive valuable preventive interventions without cost-sharing and others do not. To supplement the work being done by the expert organizations, health plans can choose to incorporate VBID principles to better align patients’ clinical and financial incentives, and thereby enhance access to high-value care.

As described above, the AMA has strong policy supporting APMs and VBID. The Councils recommend supporting initiatives that align provider-facing financial incentives created through payment reform, such as APMs, with patient-facing financial incentives created through benefit design reform, to ensure that patient, provider, and payer incentives all promote the same quality care. Such initiatives may include reducing patient cost-sharing for items and services that are tied to provider quality metrics. Additionally, the Councils recommend reaffirming Policy H-155.960 which supports VBID principles, Policy H-185.939 which supports flexibility in VBID program design, and Policy H-165.856 which supports a regulatory environment that enables private market innovation in product development and purchasing arrangements.
It may be challenging to reasonably limit what qualifies as a high-value service designated for reduced cost-sharing. Similarly, the full costs and benefits of VBID plans may only be evident over extended time horizons, so the evidence base will continue to evolve. Accordingly, rather than recommending any single plan design, it is important to support the creation of a legal and regulatory environment that cultivates innovation and freedom to experiment with transformational plan designs. At the same time, innovations in plan design should be consistent with the principles of adequacy of health insurance coverage outlined in Policy H-165.846. Specifically, the AMA should support: removing legal and regulatory barriers to innovative plan designs that seek to encourage high-value care with reduced costs to patients; promoting not only screenings to identify risk, but also high-value care to help patients manage that risk and prevent advanced disease; and allowing HSA-HDHPs to provide pre-deductible coverage for preventive and chronic care management services. In addition, the Councils recommend that as health plans experiment with innovative VBID plans, these plans incorporate the tenets of “clinical nuance” to recognize individual variation and to respect individual needs.

While continuing to advocate for legal change, there are concrete actions physicians can currently take to apply VBID principles. As plans continue to innovate around VBID, organized medicine and physicians will have a critical role in helping plans understand the highest value care they want to encourage. The exact same service may be highly valuable for some patients, but constitute over-treatment for other patients, and the physician community can lead the way in shaping policies that recognize and embrace this approach to payment reform and benefit design. Continuing with the breast cancer prevention example introduced above, for some women, the USPSTF recommended screening mammography may be all that is needed to effectively manage breast cancer risk. For other women, however, more frequent imaging can be life-saving, high-value care. While these services could be expensive in the short-term, they can prevent more likely cases of deadly (and expensive) disease.

Accordingly, it will be incumbent upon organized medicine, specifically national medical specialty societies, to collaborate with payers, educating them about the circumstances under which their specialties are providing especially high-value care, care that is most clinically important to incentivize. Physicians can work to identify and highlight the items and services within their areas of specialty that are of highest value, such as those that promote proactive healthy behaviors and/or manage risk or chronic conditions. For example, in looking to evidence-based quality metrics as indicators of high-value care, physicians of all specialties can play a critical role in shaping VBID programs to come. National medical specialty societies should collaborate with payers to shape the designation of “high-value” services and the financial and other incentives that would promote their access and utilization.

RECOMMENDATIONS

The Council on Medical Service and the Council on Science and Public Health recommend that the following be adopted and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-155.960, which supports “value-based decision-making” and reducing the burden of preventable disease as broad strategies for addressing rising health care cost; recognizes the important role of physician leadership, as well as collaboration among physicians, patients, insurers, employers, unions, and government in successful cost-containment and quality-improvement initiatives; and encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are determined based on the clinical value of a health care service or treatment, with consideration given to further tailoring cost-sharing requirements to patient income and other factors known to impact compliance.

2. That our AMA reaffirm Policy H-185.939, which supports flexibility in the design and implementation of Value-Based Insurance Design (VBID) programs and outlines guiding principles including that VBID explicitly consider the clinical benefit of a given service or treatment when determining cost-sharing or other benefit design elements, and that practicing physicians, including appropriate specialists, must be actively involved in the development of VBID programs.

3. That our AMA reaffirm Policy H-165.856, which supports a regulatory environment that enables rather than impedes private market innovation in product development and purchasing arrangements.
4. That our AMA support VBID plans designed in accordance with the tenets of “clinical nuance,” recognizing that (1) medical services may differ in the amount of health produced, and (2) the clinical benefit derived from a specific service depends on the person receiving it, as well as when, where, and by whom the service is provided.

5. That our AMA support initiatives that align provider-facing financial incentives created through payment reform and patient-facing financial incentives created through benefit design reform, to ensure that patient, provider, and payer incentives all promote the same quality care. Such initiatives may include reducing patient cost-sharing for the items and services that are tied to provider quality metrics.

6. That our AMA develop coding guidance tools to help providers appropriately bill for zero-dollar preventive interventions and promote common understanding among health care providers, payers, patients, and health care information technology vendors regarding what will be covered at given cost-sharing levels.

7. That our AMA develop physician educational tools that prepare physicians for conversations with their patients about the scope of preventive services provided without cost-sharing and instances where and when preventive services may result in financial obligations for the patient.

8. That our AMA continue to support requiring private health plans to provide coverage for evidence-based preventive services without imposing cost-sharing (such as co-payments, deductibles, or coinsurance) on patients.

9. That our AMA continue to support implementing innovative VBID programs in Medicare Advantage plans.

10. That our AMA support legislative and regulatory flexibility to accommodate VBID that (a) preserves health plan coverage without patient cost-sharing for evidence-based preventive services; and (b) allows innovations that expand access to affordable care, including changes needed to allow High Deductible Health Plans paired with Health Savings Accounts to provide pre-deductible coverage for preventive and chronic care management services.

11. That our AMA encourage national medical specialty societies to identify services that they consider to be high-value and collaborate with payers to experiment with benefit plan designs that align patient financial incentives with utilization of high-value services.

REFERENCES


APPENDIX - Policies Recommended for Reaffirmation

H-155.960, Strategies to Address Rising Health Care Costs
Our AMA:
(1) recognizes that successful cost-containment and quality-improvement initiatives must involve physician leadership, as well as collaboration among physicians, patients, insurers, employers, unions, and government;
(2) supports the following broad strategies for addressing rising health care costs: (a) reduce the burden of preventable disease; (b) make health care delivery more efficient; (c) reduce non-clinical health system costs that do not contribute value to patient care; and (d) promote “value-based decision-making” at all levels;
(3) will continue to advocate that physicians be supported in routinely providing lifestyle counseling to patients through: adequate third-party reimbursement; inclusion of lifestyle counseling in quality measurement and pay-for-performance incentives; and medical education and training;
(4) will continue to advocate that sources of medical research funding give priority to studies that collect both clinical and cost data; use evaluation criteria that take into account cost impacts as well as clinical outcomes; translate research findings into useable information on the relative cost-effectiveness of alternative diagnostic services and treatments; and widely disseminate cost-effectiveness information to physicians and other health care decision-makers;
(5) will continue to advocate that health information systems be designed to provide physicians and other health care decision-makers with relevant, timely, actionable information, automatically at the point of care and without imposing undue administrative burden, including: clinical guidelines and protocols; relative cost-effectiveness of alternative diagnostic services and treatments; quality measurement and pay-for-performance criteria; patient-specific clinical and insurance information; prompts and other functionality to support lifestyle counseling, disease management, and case management; and alerts to flag and avert potential medical errors;

(6) encourages the development and adoption of clinical performance and quality measures aimed at reducing overuse of clinically unwarranted services and increasing the use of recommended services known to yield cost savings;

(7) encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are determined based on the clinical value of a health care service or treatment. Consideration should be given to further tailoring cost-sharing requirements to patient income and other factors known to impact compliance; and

(8) supports ongoing investigation and cost-effectiveness analysis of non-clinical health system spending, to reduce costs that do not add value to patient care.

(9) Our AMA will, in all reform efforts, continue to identify appropriate cost savings strategies for our patients and the health care system.

H-165.856, Health Insurance Market Regulation
Our AMA supports the following principles for health insurance market regulation:

(1) There should be greater national uniformity of market regulation across health insurance markets, regardless of type of sub-market (e.g., large group, small group, individual), geographic location, or type of health plan.

(2) State variation in market regulation is permissible so long as states demonstrate that departures from national regulations would not drive up the number of uninsured, and so long as variations do not unduly hamper the development of multi-state group purchasing alliances, or create adverse selection.

(3) Risk-related subsidies such as subsidies for high-risk pools, reinsurane, and risk adjustment should be financed through general tax revenues rather than through strict community rating or premium surcharges.

(4) Strict community rating should be replaced with modified community rating, risk bands, or risk corridors. Although some degree of age rating is acceptable, an individual's genetic information should not be used to determine his or her premium.

(5) Insured individuals should be protected by guaranteed renewability.

(6) Guaranteed renewability regulations and multi-year contracts may include provisions allowing insurers to single out individuals for rate changes or other incentives related to changes in controllable lifestyle choices.

(7) Guaranteed issue regulations should be rescinded.

(8) Health insurance coverage of pre-existing conditions with guaranteed issue within the context of an individual mandate, in addition to guaranteed renewability.

(9) Insured individuals wishing to switch plans should be subject to a lesser degree of risk rating and pre-existing conditions limitations than individuals who are newly seeking coverage.

(10) The regulatory environment should enable rather than impede private market innovation in product development and purchasing arrangements. Specifically: (a) legislative and regulatory barriers to the formation and operation of group purchasing alliances should, in general, be removed; (b) benefit mandates should be minimized to allow markets to determine benefit packages and permit a wide choice of coverage options; and (c) any legislative and regulatory barriers to the development of multi-year insurance contracts should be identified and removed.

H-185.939, Value-Based Insurance Design
Our AMA supports flexibility in the design and implementation of value-based insurance design (VBID) programs, consistent with the following principles:

a. Value reflects the clinical benefit gained relative to the money spent. VBID explicitly considers the clinical benefit of a given service or treatment when determining cost-sharing structures or other benefit design elements.

b. Practicing physicians must be actively involved in the development of VBID programs. VBID program design related to specific medical/surgical conditions must involve appropriate specialists.

c. High-quality, evidence-based data must be used to support the development of any targeted benefit design. Treatments or services for which there is insufficient or inconclusive evidence about their clinical value should not be included in any targeted benefit design elements of a health plan.

d. The methodology and criteria used to determine high- or low-value services or treatments must be transparent and easily accessible to physicians and patients.

e. Coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Educational materials should be made available to help patients and physicians understand the incentives and disincentives built into the plan design.

f. VBID should not restrict access to patient care. Designs can use incentives and disincentives to target specific services or treatments, but should not otherwise limit patient care choices.

h. Plan sponsors should ensure adequate resource capabilities to ensure effective implementation and ongoing evaluation of the plan designs they choose. Procedures must be in place to ensure VBID coverage rules are updated in accordance with evolving evidence.

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i. VBID programs must be consistent with AMA Pay for Performance Principles and Guidelines (Policy H-450.947), and AMA policy on physician economic profiling and tiered, narrow or restricted networks (Policies H-450.941 and D-285.972).