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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 1-I-17

Subject: Affordable Care Act Section 1332 Waivers (Resolution 206-I-16)

Presented by: Paul A. Wertsch, MD, Chair

Referred to: Reference Committee J (Peter C. Amadio, MD, Chair)

At the 2016 Interim Meeting, the House of Delegates referred Resolution 206, "Advocacy and Studies on Affordable Care Act Section 1332 (State Innovation Waivers)," which was sponsored by the Medical Student Section. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2017 Interim Meeting. Resolution 206-I-16 asked:

> That our American Medical Association (AMA) advocate that the "deficit-neutrality" component of the current US Department of Health and Human Services (HHS) rule for Section 1332 waiver qualifications be considered only on long-term, aggregate cost savings of states' innovations as opposed to having costs during any particular year, including in initial "investment" years of a program, reduce the ultimate likelihood of waiver approval; and
>
> That our AMA study reforms that can be introduced under Section 1332 of the Affordable Care Act (ACA) in isolation and/or in combination with other federal waivers to improve healthcare benefits, access and affordability for the benefit of patients, healthcare providers and states, and encourages state societies to do the same.

This report provides background on Section 1332 waivers, outlines regulatory activity on Section 1332 waivers, highlights Section 1332 waiver applications and approvals, summarizes relevant AMA policy, and presents policy recommendations.

BACKGROUND

Section 1332 of the ACA established a new waiver supporting state innovation in order to enable states to experiment with and implement different models to provide health insurance coverage to their residents. Under Section 1332, some of the ACA's private insurance and coverage provisions can be waived, including those pertaining to premium tax credits and cost-sharing reductions for plans offered through the marketplaces, the individual and employer responsibility requirements and standards for health insurance marketplaces and qualified health plan standards. Other sections of the ACA cannot be waived under Section 1332, including those addressing guaranteed issue and community rating, the law's prohibition against insurers denying coverage or charging higher premiums to people with pre-existing conditions, the ban on annual and lifetime limits, and the ability of adult dependents up to age 26 to be covered on their parents' health plans.

Under Section 1332, the Secretaries of HHS and the Treasury are granted the authority to approve a request for a Section 1332 waiver only if the proposal meets the following four criteria:

1. The proposal will provide coverage to at least a comparable number of the state's residents as would be provided absent the waiver;
2. The proposal will provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state's residents as would be provided absent the waiver;
3. The proposal will provide coverage that is at least as comprehensive for the state's residents as would be provided absent the waiver; and
4. The proposal will not increase the federal deficit.

If a Section 1332 waiver is approved, a state may receive funding equal to the amount of forgone federal financial assistance that would have been provided to its residents enrolled in marketplace coverage pursuant to the ACA, a process referred to as pass-through funding. Pass-through funding is capped at the amount of forgone marketplace subsidies and does not account for any other changes in federal spending or revenues as a result of the waiver.[1] Accordingly, pass-through funding is especially essential for Section 1332 waivers under which individuals and/or small employers in the state would no longer qualify for premium tax credits, cost-sharing reductions and/or small business credits for which they would otherwise be eligible. For such waivers, the aggregate amount of such credits or reductions that would have been paid on behalf of consumers in the marketplaces had the state not received such waiver would instead be paid to the state to implement its Section 1332 waiver. Section 1332 waivers, which have been available since the beginning of this year, may be approved for periods up to five years and can be renewed.[2]

REGULATORY ACTIVITY ON SECTION 1332 WAIVERS

A final regulation addressing the application, review, and reporting process for Section 1332 waivers was issued in February 2012. Under the final regulation, a state submitting an application for a Section 1332 waiver must provide actuarial analyses and certifications, economic analyses, data and assumptions, targets, an implementation timeline, and other necessary information to show the proposed waiver's compliance with the ACA criteria for Section 1332 waivers as noted above. Specific to deficit reduction, the economic analyses submitted by the state are required to include a detailed 10-year budget plan that is deficit neutral to the federal government. The final regulation also allows states to submit a single application for a Section 1332 waiver along with existing waivers applicable to Medicare, Medicaid and the Children's Health Insurance Program (CHIP), which could include Section 1115 (of the Social Security Act) waivers, which currently allow states to implement experimental, pilot, or demonstration projects in the Medicaid and CHIP programs.[3]

In December 2015, the Centers for Medicare & Medicaid Services (CMS) and the Department of the Treasury released guidance that addressed how the agencies will evaluate state applications for Section 1332 waivers. Addressing the ACA's deficit neutrality requirement, the guidance stated that waivers must not increase the federal deficit over the period of the waiver or in total over the ten-year budget plan submitted by the state. Pertinent to referred Resolution 206-I-16, the agencies stated in the guidance that "a waiver that increases the deficit in any given year is less likely to meet the deficit neutrality requirement." In addition, the guidance stated that although a state may submit a coordinated waiver application, in such a case each waiver will be evaluated independently according to applicable federal laws. Importantly, the guidance stated that there would be limitations to Section 1332 waiver applications for states that use healthcare.gov for their marketplaces, as the federal platform cannot accommodate different rules for different states.

Therefore, the agencies note that states contemplating waivers that include changes to the calculation of marketplace financial assistance as well as plan management, for example, may consider establishing and administering their own platform.[4]

In March 2017, HHS Secretary Price sent a letter to governors encouraging states to submit Section 1332 waiver proposals, including proposals for high-risk pool/state-operated reinsurance programs. In the letter, Secretary Price referenced Alaska's waiver application, which was approved in July 2017, and sought federal support for a state-managed reinsurance program. The Secretary noted that if a state's plan under its waiver proposal is approved, a state may be able to receive pass-through funding to help offset a portion of the costs for the high-risk pool/state-operated reinsurance programs.[5]

In May 2017, CMS released a checklist for Section 1332 waiver applications, which also included specific items pertaining to applications that include high-risk pool/state-operated reinsurance programs. Pertaining to deficit neutrality, the checklist states as part of waiver applications, states must include an economic analysis to support the state's finding that the waiver will not increase the federal deficit over the five-year waiver period or in total over the ten-year budget period. Additionally, the checklist stipulates that the deficit analysis submitted by the state should show yearly changes in the federal deficit due to the waiver.[6]

SECTION 1332 WAIVER APPLICATIONS AND APPROVALS

As Section 1332 waivers have only been available starting this year, activity on waivers has been relatively limited. At the time that this report was prepared, nine states had submitted waiver applications – Alaska, California, Hawaii, Iowa, Massachusetts, Minnesota, Oklahoma, Oregon and Vermont. The waiver applications of three states - Hawaii, Alaska and Minnesota - have been approved. Of note, Minnesota's waiver was approved with less federal pass-through funding than was requested by the state. The waiver applications of California and Oklahoma were withdrawn, while Vermont's was put on hold.[7] Hawaii's Section 1332 waiver allowed the state to keep its longstanding employer coverage provisions resulting from the state's Prepaid Health Care Act, which requires employers to provide more generous coverage than is required under the ACA. As such, Hawaii's waiver sought to waive the ACA requirement that a Small Business Health Options Program (SHOP) marketplace operate in Hawaii and other provisions related to SHOP marketplaces, including the requirement that the small business tax credits could only be available through the SHOP.[8,9]

Alaska's waiver allows the state to implement the Alaska Reinsurance Program (ARP) for 2018 and subsequent years. The ARP will cover claims in the individual market for individuals with one or more of 33 identified high-cost conditions to help stabilize premiums. As a result, insurers will relinquish both premiums received for such individuals as well as claims they would have paid absent the waiver. As a result of the ARP, it is expected that premiums will be 20 percent lower in 2018 than absent the waiver, and 1,460 additional individuals will have health insurance coverage. Because the ARP will lower premiums, the second lowest cost silver plan premium is reduced, which results in the federal government spending less on premium tax credits.[10] The waiver application of Minnesota would create the Minnesota Premium Security Plan, which was estimated to yield a 20 percent reduction in average premiums in 2018.[11] While Minnesota's waiver was approved, the full amount the state requested in its waiver for federal pass-through funding to financially support its reinsurance program was not approved. Only federal pass-through funding reflecting savings from less spending on premium tax credits and cost-sharing reductions was approved, not the amount also requested by the state that reflects federal savings due to lower premiums for plans under the state's Basic Health Program.[12] The waiver application of Oregon,

which was still under review when this report was prepared, anticipates that its waiver to establish the Oregon Reinsurance Program will reduce premiums, including those for the second-lowest cost silver plan, by 7.5 percent in 2018 (net of the premium assessment), with an increase in enrollment in the individual market by approximately 1.7 percent in the same year.[13]

Likewise, Iowa's waiver application includes a reinsurance program. However, due to concerns at the time of its waiver application that there would be no insurers participating in the state's marketplace in 2018, Iowa also proposed to make substantive changes to ACA requirements, and cited the need for "emergency regulatory relief." Iowa's Section 1332 waiver proposal calls for the creation of a single Proposed Stopgap Measure plan that would be the only plan offered by insurers in the marketplace, and provide coverage similar to that offered by a standard silver plan. In addition, the initial waiver application proposes replacing the ACA's premium tax credits with flat premium subsidies based on age and income, as well as eliminating cost-sharing reductions (CSRs).[14] In response to concerns over the state's waiver application eliminating cost-sharing reductions, Iowa submitted a supplement to its waiver application in order to provide additional cost-sharing support to individuals with incomes between 133 and 150 percent of the federal poverty level (FPL), to be implemented similarly to how cost-sharing reductions are currently provided to this population.[15] Of note, cost-sharing reductions are currently provided to individuals with incomes up to 250 percent of the FPL under the ACA. In addition, the state has requested that HHS waive the requirements that Section 1332 waivers include actuarial analyses, actuarial certifications, and economic analyses, including those which support the state's finding that the waiver will not increase the federal deficit over the period of the waiver or in total over the 10-year budget period.[16] At the time that this report was prepared, Iowa no longer has any counties at risk of having no insurer participating in the state's marketplace in 2018.[17]

In response to the market volatility the uncertainty about continued funding for CSRs has caused, Massachusetts submitted a waiver request that requested waiver of CSRs and instead create a Premium Stabilization Fund that would make payments to health plans equivalent to those that would be made under federal CSR payments. Massachusetts requested expedited review of its waiver, which if approved would be effective January 1, 2018 for an initial period of at least one year, and likely blunt premium increases that would otherwise occur in the marketplace due to the uncertainty as to whether federal CSR funding will continue.[18]

RELEVANT AMA POLICY

Policy D-165.942 advocates that state governments be given the freedom to develop and test different models for covering the uninsured, provided that their proposed alternatives meet or exceed the projected percentage of individuals covered under an individual responsibility requirement while maintaining or improving upon established levels of quality of care, ensure and maximize patient choice of physician and private health plan, and include reforms that eliminate denials for pre-existing conditions. Policy H-165.845 supports outlined principles to guide in the evaluation of state health system reform proposals, including:

- Health insurance coverage for state residents should be universal, continuous, and portable. Coverage should be mandatory only if health insurance subsidies are available for those living below a defined poverty level.
- The health care system should emphasize patient choice of plans and health benefits, including mental health, which should be value-based. Existing federal guidelines regarding types of health insurance coverage (e.g., Title 26 of the US Tax Code and Federal Employees Health Benefits Program [FEHBP] regulations) should be used as references when considering if a given plan would provide meaningful coverage.

- The delivery system should ensure choice of health insurance and physician for patients, choice of participation and payment method for physicians, and preserve the patient/physician relationship. The delivery system should focus on providing care that is safe, timely, efficient, effective, patient-centered, and equitable.
- The administration and governance system should be simple, transparent, accountable, efficient, and effective in order to reduce administrative costs and maximize funding for patient care.
- Health insurance coverage should be equitable, affordable, and sustainable. The financing strategy should strive for simplicity, transparency, and efficiency. It should emphasize personal responsibility as well as societal obligations.

Policies D-165.966 and H-165.855 advocate that state governments be given the freedom to develop and test different models for improving coverage for patients with low incomes. Policy D-165.966 also supports changes in federal rules and federal financing to support the ability of states to develop and test such alternatives without incurring new and costly unfunded federal mandates or capping federal funds.

DISCUSSION

The AMA has long advocated that state governments be given the freedom to develop and test different models for improving coverage for patients with low incomes. The Council believes that Section 1332 of the ACA provides states with a unique opportunity to build upon the progress that has been made in expanding health insurance coverage and choice under the ACA. With Section 1332 waivers, states could devise new and innovative approaches to provide quality health insurance coverage to more people, as well as make health insurance coverage more affordable. The Council believes that it is imperative that approved State Innovation Waivers follow the criteria outlined in Section 1332 of the ACA and related regulations: that Section 1332 waiver proposals will provide coverage to at least a comparable number of the state's residents as would be provided absent the waiver; provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state's residents as would be provided absent the waiver; provide coverage that is at least as comprehensive for the state's residents as would be provided absent the waiver; and not increase the federal deficit.

However, additional actions should be taken, either administratively or legislatively, to make Section 1332 waivers more workable for states, and be potentially more advantageous for state residents. Under current law, Section 1332 waivers are required to not add to the federal deficit, and current guidance states that waivers must not increase the federal deficit over the period of the waiver or in total over the ten-year budget plan submitted by the state. However, the language in the federal guidance from 2015 also stated that "a waiver that increases the deficit in any given year is less likely to meet the deficit neutrality requirement." The Council believes that there could be unintended consequences for states seeking to innovate to require deficit neutrality in each individual year of a Section 1332 waiver. The Council recognizes that it would be reasonable for some waivers to project deficits in years one or two of a waiver as a result of start-up and other costs, and savings in subsequent years that offset the earlier deficits. The Council believes it is essential for Section 1332 waivers to remain deficit neutral over the period of the waiver (which may not exceed five years unless renewed), as well as in total over the ten-year budget plan submitted by the state.

The Council also believes that federal pass-through funding provided to states to implement their Section 1332 waivers should capture all federal budgetary savings achieved by the waiver. Under current law, the amount of federal pass-through funding is equal to an annual estimate of forgone

marketplace subsidies and financial assistance that would have otherwise been provided pursuant to the ACA. If a Section 1332 waiver creates additional federal savings outside of the scope of marketplace subsidies, such as reducing the cost of the tax exclusion for employer-sponsored coverage, such savings should also be included in the amount of federal pass-through funding provided to the state to finance its Section 1332 waiver.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 206-I-16, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support the criteria outlined in Section 1332 of the Affordable Care Act for the approval of State Innovation Waivers:

    a. The waiver proposal will provide coverage to at least a comparable number of the state's residents as would be provided absent the waiver;
    b. The waiver proposal will provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state's residents as would be provided absent the waiver;
    c. The waiver proposal will provide coverage that is at least as comprehensive for the state's residents as would be provided absent the waiver; and
    d. The waiver proposal will not increase the federal deficit. (New HOD Policy)

2. That our AMA support the deficit neutrality requirement of Section 1332 waivers being enforced over the period of the waiver and in total over the ten-year budget plan submitted by a state, not in each individual year of the waiver. (New HOD Policy)

3. That our AMA support legislation to allow other federal savings projected to be achieved as a result of a Section 1332 waiver, including any reductions in the cost of the tax exclusion for employer-sponsored coverage, to be included in the amount of federal pass-through funding provided to a state to subsidize state innovations. (New HOD Policy)

Fiscal Note: Less than $500.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2-I-17

Subject: Hospital Surveys and Health Care Disparities

Presented by: Paul A. Wertsch, MD, Chair

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

At the American Medical Association's (AMA) 2016 Interim Meeting, the House of Delegates adopted Policy D-450.954, "A Study on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey and Healthcare Disparities," which asked the AMA to study the impact of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) on Medicare payments to hospitals serving vulnerable populations and on potential health care disparities.

The Board of Trustees referred this issue to the Council on Medical Service for a report back to the House at the 2017 Interim Meeting. This report provides background on the purpose and use of HCAHPS surveys and the role of safety net hospitals, explains the intersection of HCAHPS scores and safety net hospitals, explores how cultural competency influences patient satisfaction and HCAHPS scores, and outlines relevant legislation. The Council recommends policy to help shield safety net hospitals from the potentially negative financial impact that hospital quality program assessments may have on hospitals that serve a disproportionate share of patients with social risk factors and policy to recognize the importance of cultural competency in patient experience and treatment plan adherence.

BACKGROUND

The HCAHPS survey is the first national, standardized, publicly reported survey of patients' perspectives of hospital care. HCAHPS has three goals.[1] First, the survey is designed to produce data about patients' perspectives of care that allow objective and meaningful comparisons of hospitals on topics that are important to patients. Second, public reporting of the survey results creates new incentives for hospitals to improve quality of care. Third, public reporting of survey results serves to enhance accountability in health care by increasing transparency of the quality of hospital care provided in return for the public investment.

HCAHPS survey scores over a three-year period influence a portion of each hospital's value-based purchasing (VBP) incentive payment. The VBP adjusts payments to hospitals under the Inpatient Prospective Payment System (IPPS) based on the quality of care delivered. The VBP adjusts Medicare's payment rate to hospitals based on a set of defined process, outcome, and experience of care measures. The measures are represented in four different areas: Clinical Care (Process and Outcomes), Patient Experience of Care (HCAHPS), Efficiency, and Safety. As noted, the patient experience of care measure is based off of HCAHPS.

Safety net hospitals play a critical role in providing health care to vulnerable populations, and it is important to ensure that efforts to improve quality of care do not exacerbate existing health care disparities. Generally, safety net hospitals are financially stressed because they are chronically underfunded and payments are low. Because of these financial constraints, safety net hospitals may have fewer nurses and are more likely to be older buildings, which are factors largely beyond the hospital's immediate control.[2]

Safety net hospitals serve many patients without the ability to pay and generally have sicker patients and a more complex patient case mix than traditional hospitals.[3] Therefore, many safety net patients have conditions that require additional resources such as social work and behavioral health care; however, the hospitals often do not have the resources to devote to these services or the financial means to provide amenities that positively affect patient satisfaction.[4]

HCAHPS SCORES AND SAFETY NET HOSPITALS

According to one recent study published in the *Archives of Internal Medicine*, hospitals that serve a disproportionate share of low-income and Medicaid patients generally scored lower than other hospitals on the HCAHPS patient experience care survey and were 60 percent less likely to meet HCAHPS performance benchmarks under the Medicare VBP program.[5] Researchers compared HCAHPS performance and improvement for safety net hospitals with other hospitals from 2007 to 2010. While scores for both groups of hospitals improved over the four year period, the performance gap between them increased. Overall, 769 hospitals that treat the largest share of low-income patients scored 5.6 percentage points lower than their 2,327 non-safety net counterparts. It is worth noting that the HCAHPS survey is only available in six languages and therefore prohibits some patients from participating.[6]

The authors of the study surmised two explanations for the disparity between the two hospital groups. One explanation was that patients in safety net hospitals have different expectations than patients in other hospitals. The other explanation was that safety net hospitals have not done as good of a job focusing on the patient issues reflected in the survey.

Safety net hospitals have pointed out that they are at a disadvantage and that their scores should be adjusted to take into consideration the diverse case mix, poverty, language barriers, and cultural issues specific to safety net hospitals. They state that the Centers for Medicare & Medicaid Services (CMS) should design incentive programs that reward safety net hospitals prior to implementing financial penalties.

HCAHPS SCORES AND CULTURAL COMPENTENCY

Communication measures account for 50 percent of the HCAHPS patient experience index. As previously stated, patient characteristics such as race, ethnicity, and language preference may impact the perception of care provided.[7] Language and communication barriers may lead to patient dissatisfaction and poor comprehension and treatment adherence.[8] Patients and families who are non-white, speak a language other than English, and are on Medicaid report lower experience scores than those commercially insured, white, and English-speaking patients and families.[9] Therefore, demographic and cultural differences seem to be important considerations in improving communication.

The National Quality Forum (NQF) has defined cultural competency as the "ongoing capacity of health care systems, organizations, and professionals to provide for diverse patient populations high-quality care that is safe, patient and family centered, evidence based, and equitable."[10]

Cultural competency has been promoted as a strategy to enhance patient satisfaction and improve organizational performance.[11]

Patient centered care has been an ongoing focus of the health care community to facilitate quality improvement.[12] It follows that taking into account demographics and culture is necessary for aligning hospital services and patient preferences. For example, a study of California hospitals found that hospitals with greater cultural competency have better scores for doctor and nurse communication, staff responsiveness, hospital rating, and hospital recommendation.[13]

RELEVANT LEGISLATION AND REGULATORY ACTIVITY

Recent legislation has addressed how to account for social risk factors in Medicare payment. The 21st Century Cures Act requires Medicare to account for a patient's background when calculating reductions in payments to hospitals under the Hospital Readmissions Reduction Program.[14] In addition, the Hospital Inpatient Prospective Payment Systems (IPPS) rule requested feedback on how to account for social risk factors in the Inpatient Quality Reporting program. Also, in response to the IMPACT Act, the Assistant Secretary for Planning and Evaluation (ASPE) sponsored a committee of the National Academies of Sciences, Engineering and Medicine to specify criteria that could be used in determining which socioeconomic status factors should be accounted for in Medicare quality and payment systems. The committee released its report in December 2016.[15] Additionally, at the direction of the Department of Health and Human Services, the National Academy of Medicine (NAM) released a report on how social risk factors may influence health care use, outcomes, and costs in Medicare payment and quality programs.[16] Importantly, both the ASPE and NAM activities found that existing data sources used to capture social risk factors are insufficient for the purposes of developing better risk adjustment methodologies.

RELEVANT AMA ACTIVITY AND POLICY

Policy H-450.946 states that the AMA will advocate for effective quality management programs that incorporate substantial input by actively practicing physicians and physician organizations.

Policy H-450.966 states that the AMA will seek an active role in any efforts to develop national medical quality and performance standards and measures; emphasize the importance of all organizations developing, or planning to develop, quality and performance standards and measures to include actively practicing physicians and physician organizations in the development, implementation, and evaluation of such efforts; and advocate that principles be used to guide the development and evaluation of quality and performance standards and measures under federal and state health system reform efforts, including that standards and measures shall have demonstrated validity and reliability, shall reflect current professional knowledge and available medical technologies, shall be linked to health outcomes and/or access to care, shall be representative of the range of health care services commonly provided by those being measured, shall account for the range of settings and practitioners involved in health care delivery, shall recognize the informational needs of patients and physicians, shall recognize variations in the local and regional health care needs of different patient populations, shall recognize the importance and implications of patient choice and preference, and shall recognize and adjust for factors that are not within the direct control of those being measured.

The AMA has numerous policies on the appropriate use of patient satisfaction surveys. Policy D-450.960 directs the AMA to urge CMS to modify the HCAHPS scoring system so that it assigns a unique value for each rating option available to patients. Policy H-450.982 states that efforts should be continued to improve the measurement of patient satisfaction and to document its

relationship to favorable outcomes and other accepted criteria of high quality care. Additionally, Policy D-385.958 directs the AMA to work with CMS and non-government payers to ensure that subjective criteria, such as patient satisfaction surveys, be used only as an adjunctive and not a determinative measure of physician quality for the purpose of physician payment and to ensure that physician payment determination, when incorporating quality parameters, only consider measures that are under the direct control of the physician. Similarly, Policy H-406.991 states that patient satisfaction surveys should be used to help improve patient care and not be used for the purpose of determining physician payment.

Consistent with the AMA's continued efforts to refine risk adjustment, Policy H-155.957 encourages further study into the possible causes of geographic variation in health care delivery and spending, with particular attention to risk adjustment methodologies and the effects of demographic factors, differences in access to care, medical liability concerns, and insurance coverage options on demand for and delivery of health care services.

Policy H-295.897 promotes cultural competency training with the goal of emphasizing cultural competence as part of professional practice and encourages training opportunities for students and residents to learn cultural competency from community health workers.

In accordance with these policies, the AMA has advocated extensively for improvements to HCAHPS. The AMA always includes a section on improvements to HCAHPS in comments related to the Medicare physician fee schedule. The AMA successfully lobbied CMS to propose removing the pain questions from HCAHPS and clarifying that HCAHPS is a hospital level survey and that it is not appropriate to tie physician compensation or measure physicians based on HCAHPS scores.

Specifically, in the AMA's recent comments on the IPPS Proposed Rule, the AMA advocated for continued refinements to HCAHPS and refinements to the risk adjustment methodology used in program measurements. Further, the AMA advocated for CMS' consideration of measuring and accounting for social risk factors in Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs noting that the AMA continues to believe that in order to ensure the quality of care furnished by physicians and hospitals is assessed as fairly as possible, social risk factors must be taken into account.

DISCUSSION

Safety net hospitals play a critical role in providing needed health care to vulnerable populations. These hospitals provide a necessary function and often have more challenging patient populations and fewer resources to devote to patient care when compared to non-safety net hospitals. While patient satisfaction scores may provide an incentive for hospitals to devote more resources to the measure, safety net hospitals generally do not have the funding to do so. Although the Council believes that the goal of such patient satisfaction surveys should be to identify areas to improve patient outcomes and quality of care, the AMA must guard against efforts aimed at improving the quality of care that have the unintentional effect of stripping safety net hospitals of needed funding and thereby exacerbating health care disparities. Tying financial incentives to HCAHPS patient satisfaction scores may have the effect of financially penalizing such hospitals and unintentionally exacerbating existing inequalities in care.[17]

Further, numerous studies have found that patient satisfaction is not necessarily an objective measure of quality. In a nationally representative sample, higher patient satisfaction was associated with lower emergency department use but with greater use of inpatient care, higher overall health care and prescription drug expenditures, and increased mortality.[18] Therefore, the limitations of

patient experience surveys should be recognized. Additionally, the Council notes that, at times, a statistically minimal number of surveys may have a material effect on overall scores. To that end, the Council recommends reaffirming numerous policies emphasizing that such quality assessments should adjust for factors outside of the physician's control and recognizing variation in different patient populations, policy stating that patient satisfaction surveys should not be a determinative measure of physician quality for payment purposes, and policy advocating for the continuation of efforts to improve patient satisfaction measurement.

Socioeconomic factors such as age, income, educational level, ethnicity and others have been identified as having a role in not only health care preferences but also health care outcomes. Such factors may present obstacles to successful outcomes and can widen health care disparities. Recognizing socioeconomic factors and focusing on cultural competency in care delivery may reduce racial and ethnic health care disparities and positively contribute to quality improvement. Therefore, the Council believes it is important not only to guard against patient satisfaction surveys unintentionally depriving safety net hospitals of needed funding but also to focus on ways to improve the patient experience. Accordingly, the Council recommends continuing to advocate for improved risk models that account for social risk factors in hospital quality program assessments. The Council notes that excluding a specific mention of HCAHPS from the recommendation and instead mentioning "hospital quality program assessments" makes the policy inclusive of the numerous hospital quality programs, including HCAHPS. Further, the Council recommends reaffirming policy promoting cultural competency training and recommends new policy recognizing the importance of cultural competency to patient experience and encouraging the implementation of such practices across health care settings.

While it may be difficult to determine whether patient satisfaction scores are a result of physician performance or demands and restrictions outside of the physician's control, the Council believes valuable information can be gleaned from patient surveys. There is evidence supporting the premise that when patients better understand treatment plans, they are more likely to adhere to recommendations and return for follow up care in the future.[19] The Joint Commission, which pools together best practices for HCAHPS scores, notes that positive patient perception of care may improve patient safety and staff retention. Additionally, patient experience of care quality and patient satisfaction are tied to the Triple Aim. Although experience may not necessarily be an indicator of quality, it is important for patient's perceptions of care to be positive. These perceptions reflect the physician-patient relationship and support patient retention and shared decision-making.

The Council believes improving the patient experience is a shared goal in health care. It also believes that ensuring the financial viability of safety net hospitals is vital to providing care to the most vulnerable and fighting to reduce health care disparities. Therefore, the Council recommends continuing to work with CMS and others, including America's Essential Hospitals, to address issues related to hospital quality program assessments.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-450.966 emphasizing that national medical quality and performance standards and measures should adjust for factors that are not within the direct control of those being measured and should recognize the variations in needs of different patient populations. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy D-385.958, which calls for the AMA to work with Centers for Medicare & Medicaid Services (CMS) and non-government payers to ensure that subjective criteria, such as patient satisfaction surveys, should not be used as a determinative measure of physician quality for the purpose of physician payment and to ensure that physician payment determination, when incorporating quality parameters, only consider measures that are under the direct control of the physician. (Reaffirm HOD Policy)

3. That our AMA reaffirm Policy H-450.982 stating that efforts should be continued to improve the measurement of patient satisfaction and to document its relationship to favorable outcomes and other accepted criteria of high quality. (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-295.897 promoting cultural competency training with the goal of emphasizing cultural competence as part of professional practice. (Reaffirm HOD Policy)

5. That our AMA support that the goal of hospital quality program assessments should be to identify areas to improve patient outcomes and quality of patient care. (New HOD Policy)

6. That our AMA recognize the importance of cultural competency to patient experience and treatment plan adherence and encourage the implementation of cultural competency practices across health care settings. (New HOD Policy)

7. That our AMA support that hospital quality program assessments should account for social risk factors so that they do not have the unintended effect of financially penalizing safety net hospitals and exacerbating health care disparities. (New HOD Policy)

8. That our AMA continue to advocate for better risk models that account for social risk factors in hospital quality program assessments. (New HOD Policy)

9. That our AMA continue to work with CMS and other stakeholders, including representatives of America's Essential Hospitals, to address issues related to hospital quality program assessments. (New HOD Policy)

10. That our AMA rescind Policy D-450.954. (Rescind HOD Policy)

Fiscal Note: Less than $500.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3-I-17

Subject: Non-Physician Screening Tests (Resolution 901-I-16)

Presented by: Paul A. Wertsch, MD, Chair

Referred to: Reference Committee J (Peter C. Amadio, MD, Chair)

At the American Medical Association's (AMA) 2016 Interim Meeting, the House of Delegates referred Resolution 901, "Disclosure of Screening Test Risk and Benefits Performed without a Doctor's Order," submitted by the American College of Radiology, and the Virginia, Alabama, Georgia, Kentucky, District of Columbia, Mississippi, West Virginia, and South Carolina Delegations. The Board of Trustees referred this issue to the Council on Medical Service for a report back to the House at the 2017 Interim Meeting. Resolution 901-I-16 asked:

> That our AMA (1) advocate that if a screening test is being marketed as having a medical benefit and is offered and performed by a wellness program vendor without a specific order by the individual's physician or other licensed provider, they must provide the patient with the test specific evidence based guidance that supports the utility of the test; (2) advocate that if the procedure is not supported by specific evidence based guidance as a screening test for that patient and the patient still would like the screening test, the Wellness Program Vendor must offer the patient the opportunity to discuss the risks, benefits, and alternatives with a physician licensed to practice medicine in the state in which the test is being performed; (3) engage with federal regulators on whether vendors of health and wellness programs are in compliance with regulations applicable to marketing to patients in view of the impact of such programs on patients; and (4) where possible, continue to work with state medical societies, interested medical specialty societies and state agencies to provide public education regarding appropriate use of vendor wellness programs.

This report provides background on wellness program vendors, particularly focusing on employer-offered wellness programs, discussion on payment for vendor screenings, an overview of the clinical guidelines for screenings, an outline of the relevant legislation, and a series of policy recommendations regarding vendor wellness screenings.

BACKGROUND

Much of today's health care system was created to provide diagnosis and treatment versus wellness and prevention. However, not only are many diseases preventable but also there are sustained concerns about health care spending. Accordingly, recent years have brought a focus on wellness and prevention. Codified in statutes like the Affordable Care Act (ACA), wellness programs have become a cornerstone in employer and health plan behavior.

More than 5,600 vendors reportedly generate annual revenue of $8 billion in the wellness industry, of which $6 billion is attributable to the workplace wellness industry.[1] Many employers now provide wellness programs to employees in an effort to help employees maintain their health and reduce health care costs. The workplace wellness industry generally consists of vendors that sell companies stand-alone wellness programs or programs that are an optional part of the employee's health insurance. In addition, some screening services are provided outside of the employer-based wellness program and are often accessed at wellness centers. The Council notes that the scope of this report is limited to basic screenings by a wellness vendor and does not encompass genetic testing. Notably, CMS/CSAPH Joint Report, "Precision Medicine," also presented at the 2017 Interim Meeting, addresses payment and coverage of genetic testing.

Several companies market wellness screenings, personalized health screenings, and biometric screenings. These services are performed outside of the traditional patient-physician setting and are often marketed to employers as wellness screening programs for their employees. The services provided vary, but they usually include a number of blood tests; ultrasound imaging for conditions, such as abdominal aortic aneurysm, carotid artery disease, and bone density; ankle-brachial index for peripheral artery disease and cardiovascular disease; and sometimes electrocardiogram. Other services include body composition analysis (e.g., body fat percentage, visceral fat, muscle mass and distribution, body water balance, total body weight, body mass index).

The increasing availability of direct-to-consumer screening tests may undermine physician efforts to provide high-quality, cost-conscious screening services to patients through shared decision-making. The wellness vendor screening services at issue are not usually administered by physicians but instead by technicians or other non-physician health professionals outside of traditional health care settings. However, many of these vendor companies have physicians as part of their leadership teams serving as medical directors or members of an advisory board. Some companies are located in retail settings, and others offer services via the internet. Occasionally, the websites of these vendor companies include a disclaimer encouraging those who are interested in testing, or those who have received abnormal test results, to contact their physicians with questions. Some companies offer follow-up with a physician staff member if patients have questions about results.

PAYING FOR WELLNESS SCREENING TESTS

Employers continue to show interest in wellness and screening programs that help employees identify health issues and manage chronic diseases. Therefore, many firms pay for such screenings and tests and some offer financial incentives to encourage employees to complete the health assessments.[2] Many large employers offering health assessments, biometric screenings, and wellness programs offer participating employees lower premium contributions or reduced cost-sharing.[3]

Outside of the workplace wellness program paradigm, health insurance generally does not cover screenings that have not been recommended by physicians. Further, vendors generally make more money the more screenings they perform and therefore often recommend screenings for otherwise healthy people, a practice that has the effect of increasing overall health care costs.[4]

CLINICAL GUIDELINES FOR WELLNESS SCREENINGS

There is concern that the screening services provided by wellness vendors are not always supported by clinical guidelines. Vendor programs do not need to follow screening guidelines from the US Preventive Services Task Force (USPSTF) or other guideline-making bodies. For example, the USPSTF found insufficient evidence to recommend several wellness tests including high sensitivity

C-reactive protein testing for coronary heart disease risk and ankle-brachial index to determine risk for peripheral artery disease and cardiovascular disease.[5] Additionally, concerns exist about providing screening tests to large numbers of patients who may not need them. Wellness programs offer blanket screening tests for nearly anyone while most screening guidelines are tailored based on age, gender, and other factors. For example, the USPSTF recommends abdominal aortic aneurysm screening only in men ages 65-75 who are or have been smokers, and when these guidelines are not followed it leads to unnecessary tests for which a given individual may have no indication. Additionally, the larger the screened population, the higher the number of false positive and false negative results. False positive results could set off a cascade of invasive, expensive, and potentially harmful follow-up tests, and false negative results could lead patients to forego necessary care.

EFFECTIVENESS OF WELLNESS PROGRAMS

The return on investment for wellness programs and screenings is mixed. Often the programs fail to pay for themselves and confer no proven health benefit.[6] Commonly, wellness programs focus on two components: a lifestyle management program and a disease management program. The lifestyle management program focuses on individuals with health risks such as obesity and smoking while the disease management program is designed to help those who already have a chronic disease.[7] Programs focusing on disease management provide a greater return on investment than lifestyle management.[8] Overall, it is estimated that wellness programs reduced average health care costs by about $30 per member per month; however, 87 percent of savings were attributable to disease management programs that focus on interventions for individuals with already-diagnosed conditions in order to reduce complications and related health care utilization.[9] Additionally, it is expensive for employers to pay for wellness program screenings and incentives, and interventions such as subsidizing healthy food choices and reimbursing employees for gym memberships may prove more beneficial.[10,11]

RELEVANT REGULATIONS

Many states have laws allowing patients to order their own laboratory tests. Additionally, the claims of efficacy made by the vendors are subject to Federal Trade Commission rules on truth-in-advertising, and therefore the claims must be truthful, not misleading, and must be substantiated. Many companies providing these services include language on their websites and other publications stating that test results do not constitute medical advice or diagnoses, thereby limiting their liability.

In response to public health concerns over an unregulated industry, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) to establish standards for diagnostic testing including standards related to safety guidelines, standards to ensure the accuracy and reliability of test results, and standards for laboratory staff, including appropriate level of training.[12] In order to operate, wellness vendors are expected to comply with these guidelines with respect to good practices and may then apply for and receive CLIA certification. Three federal agencies are responsible for the CLIA: The Food and Drug Administration, the Centers for Medicare and Medicaid Services, and the Centers for Disease Control and Prevention.[13] Eighteen states have rules and regulations in addition to CLIA, and some states require vendor licensure in their public health codes.[14]

Additionally, wellness programs must comply with a host of federal laws. These laws include the Employee Retirement Income Security Act (ERISA), the Americans with Disabilities Act (ADA), the Genetic Information Nondiscrimination Act (GINA), the ACA, and the Health Insurance Portability and Accountability Act (HIPAA).[15] HIPAA applies to wellness programs offered as part

of an employer's group health plan. Therefore, information collected from or created about participants in the wellness program as part of the group health plan is considered personal health information and is protected by HIPAA.[16]

RELEVANT AMA POLICY AND ADVOCACY

Policy H-425.996 on multiphasic health screening programs states that entities that operate or sponsor such multiphasic health screening programs should be urged to include in their promotional and explanatory materials about the availability of the program, a definitive statement that reports on the screening test results will be furnished to the individual participants only and that each participant is responsible for obtaining any needed medical evaluation or follow-up should the results of the tests deviate from the normal range. Those operating or sponsoring multiphasic health screening programs also should be urged to utilize report forms that state in bold type that the report does not constitute a medical diagnosis or evaluation and that the participant should consult a physician of his or her choice if the screening test results are not within the normal limits indicated on the report. Policy H-425.997 more generally states that preventive care should ideally be coordinated by a patient's physician.

Policy H-425.994 states that the evaluation of a healthy person by a physician can serve as a convenient reference point for preventive services and for counseling about healthful living and known risk factors and that the testing of individuals should be pursued only when adequate treatment and follow-up can be arranged for the abnormal conditions and risk factors identified.

To promote continuity of care, Policy H-160.921 states that retail health clinics must establish protocols for ensuring continuity of care with practicing physicians within the local community and that retail health clinics should be encouraged to use electronic health records as a means of communicating patient information and facilitating continuity of care. Further, Policy H-160.921 states that retail health clinics should encourage patients to establish care with a primary care physician to ensure continuity of care.

Policy D-35.985 recognizes non-physician providers as valuable components of the physician-led health care team. With respect to the health care team, Policy H-275.976 states that the health professional who coordinates an individual's health care has an ethical responsibility to ensure that the services rendered are provided by those whose competence and performance are suited to render those services safely and effectively.

Policy H-330.879 on providers and Medicare's Annual Wellness Visit (AWV) articulates principles reinforcing the need to protect against vendors fragmenting care and the need to preserve the physician-patient relationship. Specifically, Policy H-330.879 recognizes the need for safeguards in such circumstances and states that the AWV is a benefit most appropriately provided by a physician or a member of the physician-led health care team that establishes or continues to provide ongoing continuity of care. Further, this policy supports that, at a minimum, any clinician performing the AWV must enumerate all findings from the visit and make provisions for all appropriate follow-up care.

DISCUSSION

Though well intentioned, the wellness industry often has the effect of duplicating care that physicians are already providing, unnecessarily increasing physician workload, and obstructing the physician-patient relationship.[17] The Council believes wellness programs often incentivize unnecessary testing and practices that are contrary to evidence-based medicine and medical

judgment. Accordingly, the Council offers a number of principles intended to address these issues and advance the goal of reducing cost of care that does not add value and promoting quality care.

If protections are in place, evidence-based wellness programs can have a positive impact on health by encouraging healthy behaviors and proper disease management strategies. To that end and consistent with the intent of Resolution 901-I-16, the Council recommends that wellness program vendors must disclose for whom a screening test is indicated on the basis of accepted evidence-based guidelines. Additionally, the Council believes vendors must inform patients of the potential benefits and risks of performing a test and of positive or negative screening test results before a test is performed. The Council believes these principles will help bring vendor practices in line with evidence-based guidelines and aid patients in informed decision-making.

Further, the Council believes it is important that wellness program vendors disclose the qualifications of any individual performing the test as well as those individuals interpreting the test results. Moreover, wellness program vendors should use local physicians as medical directors or supervisors. These recommendations advance the goals of patient education and recognition that physicians are best suited to lead health care teams pursuant to AMA policy. In addition, the Council believes it is important that any policy on vendor screenings limits a physician's liability and protects against physician administrative burden. To that end, the Council recommends that results of a screening test should only be sent to the individual and that test results showing a positive or otherwise abnormal test result should require a consultation with the patient's primary care physician or usual source of care. Additionally, the Council recommends that physicians not be held liable for delayed or missed diagnoses indicated on third party vendor tests. The Council believes that this recommendation expressly reaffirms the rule that physician liability be limited when stemming from tests that have not been shared with the physician. Finally, the Council believes that Policy H-425.996 is outdated and that its recommendations herein regarding non-physician screenings supersede the policy and therefore recommends that Policy H-425.996 be rescinded.

The following recommendations complement the body of AMA policy on non-physician tests and care including that on the Medicare Annual Wellness Visit and retail health clinics. The Council approaches this issue with the belief that, if proper safeguards and guidelines are in place, such wellness program vendors can have an appropriate role in the health care system and help advance the goals of better, more cost effective care.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 901-I-16 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-425.994 stating that the evaluation of a healthy person by a physician can serve as a convenient reference point for preventive services and for counseling about healthful living and known risk factors. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy H-425.997 stating that preventive care should be coordinated by a patient's physician and encouraging development of policies and mechanisms to assure the continuity, coordination, and continuous availability of patient care, including preventive care and early-detection screening services. (Reaffirm HOD Policy)

3. That it be the policy of our AMA that any wellness program vendor providing non-physician ordered screenings should adhere to the following principles:

    a. Must disclose for whom a screening test is indicated on the basis of accepted evidence-based guidelines;

    b. Must inform patients of the potential benefits and risks of performing a test and of the implications of positive or negative screening test results before a test is performed;

    c. Must disclose the qualifications of any persons in contact with the patient and of any persons interpreting the results of any screening test;

    d. Should use local physicians as medical directors or supervisors in the appropriate specialty with the requisite state licensure;

    e. Should send results of any screening only to the individual patient; and

    f. Should require a consultation with the patient's primary care physician or usual source of care if a screening test shows a positive or otherwise abnormal test result. (New HOD Policy)

4. That our AMA support that physicians not be held liable for delayed or missed diagnoses indicated on wellness program vendor non-physician ordered screenings. (New HOD Policy)

5. That our AMA rescind Policy H-425.996. (Rescind HOD Policy)

Fiscal Note: Less than $500.

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REPORT 4 OF THE COUNCIL ON MEDICAL SERVICE (I-17)
Health Insurance Affordability: Essential Health Benefits and Subsidizing the Coverage of High-Risk Patients
(Reference Committee J)

EXECUTIVE SUMMARY

As the House of Representatives and the Senate have been discussing and crafting legislation related to health reform, the Council spent the past year reviewing the substantial body of American Medical Association (AMA) policy pertaining to the AMA proposal for reform, as well as assessing whether to potentially revisit policy on certain health reform issues. The Council has concluded that the preponderance of AMA policy regarding coverage, choice and access remain relevant. However, in its review, the Council determined that it was necessary to revisit and modify policy on essential health benefits and the relative merits of high-risk pools versus reinsurance.

The Council believes there is an opportunity to include additional safeguards in AMA policy to ensure that patients have meaningful coverage that protects them against catastrophic expenses. While the AMA has long supported patient choice of health plan, AMA policy has also stressed that any health insurance purchased must provide meaningful coverage for hospital, surgical and medical care; protect patients against catastrophic expenses; and promote preventive services. AMA policy also underscores that provisions must be made to assist individuals with low-incomes or unusually high medical costs in obtaining health insurance coverage and meeting cost-sharing obligations, and that prohibitions on annual and lifetime limits should remain in place under any reform.

The Council notes that most of the health care claims costs associated with essential health benefits (EHB) are attributable to such services as hospital inpatient and outpatient care, physician services, and prescription drugs. These services are arguably viewed as fundamental components of health insurance coverage. Removing any benefits from the EHB requirements, or allowing waivers of such requirements, can cause insurers to cherry pick patients based on the services their plans cover, as well as hinder patient access to necessary services. If insurers are allowed to offer plans with skimpier coverage, plan designs could potentially discriminate against people with pre-existing conditions. In addition, individuals who use services and benefits no longer included in the EHBs could face substantial increases in out-of-pocket costs. As such, the Council is recommending that our AMA oppose the removal of categories from the EHB package. In addition, the Council believes that our AMA should also oppose waivers of EHB requirements that lead to EHB categories and their associated protections against annual and lifetime limits, and out-of-pocket expenses, being eliminated.

In addition, the Council re-evaluated AMA policy with respect to how to best subsidize the costs of high-cost and high-risk patients, who may have pre-existing conditions. Traditional high-risk pools have historically provided individuals with pre-existing conditions with second-class insurance, with waiting periods to get pre-existing conditions covered, higher premiums, potentially high deductibles, and lifetime limits on benefits. Considering the success of the Affordable Care Act's reinsurance program, as well as state reinsurance programs, and in light of finite resources, the Council believes that resources should be directed to reinsurance programs. Reinsurance provides an equitable, fair and cost-effective mechanism to subsidize the costs of high-risk and high-cost patients, and protects patients with pre-existing conditions.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-I-17

Subject: Health Insurance Affordability: Essential Health Benefits and Subsidizing the Coverage of High-Risk Patients

Presented by: Paul A. Wertsch, MD, Chair

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

The American Medical Association (AMA) proposal to cover the uninsured and expand choice, used in AMA advocacy leading up to and following the enactment of the Affordable Care Act (ACA) and highlighted in AMA's Voice for the Uninsured campaign, is based on numerous policies developed and/or refined by the Council on Medical Service, and adopted by the House of Delegates, during the 1990s and 2000s. The proposal removed the bias toward employment-based insurance and promoted a system of individually selected and owned health insurance coverage, using tax credits, individual responsibility, and other market regulations to maximize coverage gains, make coverage affordable, and ensure patient choice of health plan and physicians.

As the House of Representatives and the Senate have been discussing and crafting legislation related to health reform, the Council spent the past year reviewing the substantial body of AMA policy pertaining to the AMA proposal for reform, as well as assessing whether to potentially revisit policy on certain health reform issues. The Council has concluded that the preponderance of AMA policy regarding coverage, choice and access remain relevant. However, in its review, the Council determined that it was necessary to revisit and modify policy on essential health benefits and the relative merits of high-risk pools versus reinsurance.

This report provides background on the issues of essential health benefits, high-risk pools and reinsurance; assesses their impact on health insurance affordability; summarizes relevant AMA policy; and presents policy recommendations.

ESSENTIAL HEALTH BENEFITS

Background

Under the ACA, all qualified health benefits plans, with the exception of grandfathered individual and employer-sponsored plans, are required to offer at least the essential health benefits (EHB) package, including those offered in health insurance marketplaces and in the individual and small group markets outside of the marketplaces. The ACA specified that the EHB package must cover the following general categories of services:

- Ambulatory patient services;
- Emergency services;
- Hospitalization;
- Maternity and newborn care;
- Mental health and substance use disorder services, including behavioral health treatment;

- Prescription drugs;
- Rehabilitative and habilitative services and devices;
- Laboratory services;
- Preventive and wellness services and chronic disease management; and
- Pediatric services, including oral and vision care.

The Secretary of the US Department of Health and Human Services (HHS) has the responsibility to determine the scope of the EHB package, which the ACA specified should be equal to the scope of benefits under a typical employer-sponsored plan. Regulations addressing EHB stated that EHB shall be defined by state-specific benchmark plans. HHS also stated that "the EHB-benchmark plan would serve as a reference plan, reflecting both the scope of services and limits offered by a typical employer plan in that state." HHS outlined four benchmark plan options for states:

- The largest plan by enrollment in any of the three largest small group insurance products in the state's small group market;
- Any of the largest three state employee health benefit plans by enrollment;
- Any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by enrollment; and
- The largest insured commercial non-Medicaid health maintenance organization operating in the state.[1]

Impact on Health Insurance Affordability

Concerns have been raised that certain categories of essential health benefits drive up premium costs. The Council notes that most of the health care claims costs associated with essential health benefits are attributable to such services as hospital inpatient and outpatient care, physician services, and prescription drugs. These services are arguably viewed as fundamental components of health insurance coverage. For example, Milliman estimated that removing maternity coverage from insurance coverage may lower premiums by $8 to $14 per month, depending on geographic, provider and other factors.[2] In addition, a recent analysis conducted by RAND researchers projected that, for 2017, maternity care would account for four percent of per capita insurer spending, and mental health and substance abuse treatment would account for one percent of per capita insurer spending. Spending on prescription drugs was projected to be more substantial, accounting for approximately 22 percent of per capita insurer spending.[3]

The ACA also prohibits annual and lifetime limits, but only for care that is considered to be under the umbrella of EHBs. In addition, the ACA requires health plans to cap out-of-pocket expenses of enrollees, but only for care that is considered EHBs. As such, several analyses have concluded that if EHB categories are removed or allowed to be waived, premiums would decrease, but individuals who use services and benefits no longer included in the EHBs could face substantial increases in out-of-pocket costs.[4,5,6,7] If EHB categories are removed or allowed to be waived, health plans could react in multiple ways, including no longer covering affected categories; providing a level of coverage for affected categories (but caps on out-of-pocket spending, as well as annual and lifetime limits may not apply); or offer coverage "riders" for affected categories. Analyses have found that categories most likely to be removed from the EHB, if states are allowed flexibility to do so, include maternity care; mental health and substance abuse benefits; rehabilitative and habilitative services; certain pediatric services, including oral and vision care; and prescription drugs.[8,9,10,11] The Council notes, for example, that riders for maternity services were available prior to enactment of the ACA. In addition, if prescription drugs were removed as an EHB category, plans may provide a level of coverage for them, but individuals who rely on expensive prescription drugs

could face an exponential increase in out-of-pocket spending due to the loss of the ACA's financial protections afforded to EHB categories.

In addition, analyses have found that removing EHB categories or allowing EHB waivers could cause market segmentation.[12,13,14] If categories are removed from EHB, individuals who do not foresee a need for removed services will be attracted to more affordable, less comprehensive plans. However, individuals in need of affected services, which could range from mental health to maternity services to pediatric services, would either not have any plan options or face much higher premiums for plans that offer at least some level of coverage for removed services. As such, health plans would be able to structure their offerings as to attract lower-risk and healthier enrollees, as sicker, higher-risk individuals would tend to gravitate toward richer, more generous coverage.

Finally, concerns have been raised that removing EHB categories or allowing waivers of EHBs could allow for mini-meds and other "sham" health insurance to have greater standing in the marketplace. As ACA's protections against catastrophic costs are tied to EHBs, if EHBs are eliminated, individuals could increasingly enroll in health insurance coverage that does not protect them against catastrophic expenses. Notably, the health reform debates in the House of Representatives and the Senate have been impacted by the Congressional Budget Office's definition of private health insurance coverage, which has been outlined as "consisting of a comprehensive major medical policy that, at a minimum, covers high-cost medical events and various services, including those provided by physicians and hospitals… The definition excludes policies with limited insurance benefits (known as mini-med plans); 'dread disease' policies that cover only specific diseases; supplemental plans that pay for medical expenses that another policy does not cover; fixed-dollar indemnity plans that pay a certain amount per day for illness or hospitalization; and single-service plans, such as dental-only or vision-only policies. In this estimate, people who have only such policies are described as uninsured because they do not have financial protection from major medical risks."[15]

AMA Policy Relevant to Essential Health Benefits

Policy H-165.846 states that existing federal guidelines regarding types of health insurance coverage (e.g., Title 26 of the US Tax Code and Federal Employees Health Benefits Program [FEHBP] regulations) should be used as a reference when considering if a given plan would provide meaningful coverage. The policy also advocates that the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program be used as the model for any EHB package for children. Policy H-165.865 states that in order to qualify for a tax credit for the purchase of individual health insurance, the health insurance purchased must provide coverage for hospital care, surgical and medical care, and catastrophic coverage of medical expenses as defined by Title 26 Section 9832 of the US Code. Policy H-165.848 states that under an individual mandate, individuals should be required to obtain, at a minimum, coverage for catastrophic health care and evidence-based preventive health care. Policy D-180.986 states that our AMA will encourage local, state, and federal regulatory authorities to aggressively pursue action against "sham" health insurers. Policy H-165.856 cautions that benefit mandates should be minimized to allow markets to determine benefit packages and permit a wide choice of coverage options. Policy H-185.964 opposes new health benefit mandates unrelated to patient protections, which jeopardize coverage to currently insured populations.

HIGH-RISK POOLS AND REINSURANCE

Background

The ACA established risk adjustment, reinsurance, and risk corridor programs to not only stabilize premiums during the early years of ACA implementation, but to blunt the impact of adverse risk selection. ACA's risk adjustment program, which is permanent in nature, redistributes funds from plans with lower-risk enrollees to plans with higher-risk enrollees, thereby removing insurer incentives to "cherry pick" healthier enrollees. The ACA's temporary reinsurance program played a role in stabilizing premiums in the individual marketplace during the early years of ACA implementation. The program provided payments to plans that enrolled higher-cost individuals whose costs exceeded a certain threshold, also known as an attachment point, up to the reinsurance cap. The ACA's temporary risk corridor program aimed to promote accurate premiums while there was uncertainty among insurers in the early years of the marketplaces about who would enroll and the cost of their care. The risk corridor program limited health plan losses and gains beyond an allowable range.[16]

The ACA established a temporary state-based high-risk pool program, known as the Pre-Existing Condition Insurance Plan (PCIP) program, in 2010, to be phased out when the key coverage provisions of the ACA became operational in 2014. HHS ran the PCIPs in 23 states and the District of Columbia, while 27 states administered their own programs. Individuals had to be uninsured for at least six months before enrolling, but otherwise, the program had no pre-existing condition exclusions. Unlike traditional state high-risk pools that existed before the ACA, PCIP premiums were able to vary by age but were otherwise equal to premiums paid by individuals without pre-existing conditions. In addition, there were no annual or lifetime dollar limits on covered benefits under PCIP, there were caps on out-of-pocket spending, and there was a minimum actuarial value of plans, which impacted deductibles. The ACA appropriated $5 billion to fund net losses of PCIP programs.[17]

While the CBO estimated in June 2010 that an average of 200,000 individuals would be enrolled in PCIP for the 2011-2013 period,[18] PCIP enrollment peaked at about 115,000 in March 2013. Also in March 2013, new PCIP enrollment had to be suspended in order to ensure that there were sufficient resources to pay the claims of individuals already enrolled. Between September 2012 and September 2013, the final 12-month period for which PCIP expense data were reported, PCIP had net losses of more than $2 billion, with $4 billion in total net losses reported as of September 2013.[19]

Impact on Health Insurance Affordability

Mechanisms to subsidize the costs of high-risk and high-cost enrollees have had various rates of success. Concerning high-risk pools, prior to implementation of the ACA, 35 states offered high-risk pools as a mechanism to cover high-risk and high-cost residents, including those with pre-existing conditions. At their peak, state high-risk pools that existed prior to passage of the ACA covered more than 200,000 people nationally, with combined net losses for the state high-risk pools totaling more than $1.2 billion for 2011, or $5,510 per enrollee, on average. Overall, state high-risk pools featured premiums above standard non-group market rates, with most states capping them at 150 to 200 percent of standard rates. Many also featured high deductibles, including deductibles in the $5,000 range. Nineteen states had some degree of premium subsidy for low-income individuals. In addition, despite the fact that many individuals had to seek coverage in high-risk pools because of a pre-existing condition, most states excluded coverage for these conditions for medically eligible individuals ranging from six to 12 months. Almost all high-risk

pools imposed lifetime limits on covered services, with some also imposing annual limits on covered benefits. A few states capped or closed enrollment.[20]

The Council notes that a January 2017 report from the American Academy of Actuaries also raised concerns regarding high-risk pools, noting that "enrollment has generally been low, coverage has been limited and expensive, they require external funding, and they have typically operated at a loss… Removing high-risk individuals from the insured risk pools reduces costs in the private market only temporarily. Over time, even lower-cost individuals in the individual market can incur high health care costs, which would put upward pressure on premiums."

The actuaries also noted that funding could be directed toward a reinsurance program that reimburses plans the costs of high-risk enrollees. For example, to fund the ACA's transitional reinsurance program, insurers and third party administrators paid $63 per enrollee per year in 2014, $44 in 2015 and $27 in 2016. These investments in reinsurance yielded premium reductions. For example, in 2014, the $10 billion reinsurance fund, the result of the $63 per enrollee per year contributions, was estimated to reduce premiums by 10 to 14 percent. The actuaries stated that a permanent program to reimburse plans for the costs of their high-risk enrollees would reduce premiums.[21] Reinsurance enables high-risk enrollees to remain in the same individual market risk pool and enjoy the same protections and choices as healthy plan enrollees.

States have also submitted waivers under Section 1332 of the ACA, as outlined in Council on Medical Service Report 1 being considered at this meeting, to fund state reinsurance programs. Alaska's waiver, which has been approved, allows the state to implement the Alaska Reinsurance Program (ARP) for 2018 and subsequent years. The ARP will cover claims in the individual market for individuals with one or more of 33 identified high-cost conditions to help stabilize premiums. As a result, insurers will relinquish both premiums received for such individuals as well as claims they would have paid absent the waiver. As a result of the ARP, it is expected that premiums will be 20 percent lower in 2018 than absent the waiver, and 1,460 additional individuals will have health insurance coverage.[22] The waiver application of Minnesota, which has also been approved, would create the Minnesota Premium Security Plan, which was estimated to yield a 20 percent reduction in average premiums in 2018.[23] While Minnesota's waiver was approved, the full amount the state requested in its waiver for federal pass-through funding to financially support its reinsurance program was not approved. Only federal pass-through funding reflecting savings from less spending on premium tax credits and cost-sharing reductions was approved, not the amount also requested by the state that reflects federal savings due to lower premiums for plans under the state's Basic Health Program.[24] The waiver application of Oregon, which was still under review when this report was prepared, anticipates that its waiver to establish the Oregon Reinsurance Program will reduce premiums, including those for the second-lowest cost silver plan, by 7.5 percent in 2018 (net of the premium assessment), with an increase in enrollment in the individual market by approximately 1.7 percent in the same year.[25]

Maine also had an "invisible high-risk pool" that it implemented in 2011, which in functionality was more similar to a reinsurance program than a high-risk pool. The main difference between invisible high-risk pools and the more traditional approach to reinsurance as included in the ACA is that the pools identify potential high-cost individuals prospectively, versus being reimbursed retrospectively for patients who actually incur high-cost claims. As a result, some plan enrollees who end up having unpredictably costly claims may not be included in invisible high-risk pools, and as such insurers would not be reimbursed for a portion of their claims. For example, under Maine's program, all health insurance applicants were required to complete a health statement with their application for insurance, and insurers used the statement to ascertain which individuals to place in the invisible high-risk pool, based on what health conditions they had. Selected individuals

were enrolled in the same plan they applied for at the same premium levels, but on the back-end, their health insurers were reimbursed for 90 percent of their claims between $7,500 and $32,500 per year and 100 percent of claims more than $32,500. Premium reductions were achieved as a result, which varied based on applicant age.[26]

AMA Policy Relevant to Risk Subsidization

Policy H-165.842 supports the principle that health insurance coverage of high-risk patients be subsidized through direct risk-based subsidies such as high-risk pools, risk adjustment, and reinsurance, rather than through indirect methods that rely heavily on market regulation; and supports state-based demonstration projects to subsidize coverage of high-risk patients through mechanisms such as high-risk pools, risk adjustment, reinsurance, and other risk-based subsidies.

Policy H-165.995 supports: (1) the establishment in each state of a risk pooling program, in which all health care underwriting entities in the state participate, to provide adequate health insurance coverage at a premium slightly higher than the standard group rate to (a) those who are unable to obtain such coverage because of medical considerations, and (b) those with medically standard risks who could afford, but presently lack, access to such group coverage; (2) the amendment of the federal tax code to require employers to purchase group health insurance coverage from an entity participating in the state risk pool or, if self-insured, to participate in the risk pool if such a pool is available, in order to deduct the cost of their coverage as a business expense; and (3) using state tax revenues as an alternative source for defraying excess pool costs.

DISCUSSION

As millions of Americans have gained coverage resulting from the ACA, the Council affirms that progress has been made on a long-time policy priority of the AMA – expanding access to affordable, quality health insurance coverage. However, in light of the health reform discussions and debates that have occurred this year, the Council believes there is an opportunity to include additional safeguards in AMA policy to ensure that patients have meaningful coverage that protects them against catastrophic expenses. While the AMA has long supported patient choice of health plan, AMA policy has also stressed that any health insurance purchased must provide meaningful coverage for hospital, surgical and medical care; protect patients against catastrophic expenses; as well as promote preventive services. AMA policy also underscores that provisions must be made to assist individuals with low-incomes or unusually high medical costs in obtaining health insurance coverage and meeting cost-sharing obligations, and that prohibitions on annual and lifetime limits should remain in place under any reform.

Under current law, the requirement that all qualified health plans, with the exception of grandfathered individual and employer-sponsored plans, offer at least the EHBs in the EHB package, has helped ensure that individuals have had access to meaningful coverage. Importantly, the prohibition on annual and lifetime limits, as well as the cap on out-of-pocket expenses, is only required for care that is considered to be under the umbrella of essential health benefits. Consistent with previously established AMA policy, the Council believes that using the current benchmark approach to EHBs, while requiring ten categories of essential health benefits, strikes a balance between offering meaningful coverage and maintaining patient choice in health plans and their respective benefits packages. The Council believes that the benchmark approach to EHBs recognizes that there is not a “one size fits all” approach to health insurance benefits, and that some variability is needed.

The Council notes that most of the health care claims' costs associated with EHBs are attributable to such services as hospital inpatient and outpatient care, physician services, and prescription drugs. These services are arguably viewed as fundamental components of health insurance coverage. Removing any benefits from the EHB requirements, or allowing waivers of such requirements, can cause insurers to cherry pick patients based on the services their plans cover, as well as hinder patient access to necessary services. If insurers are allowed to offer plans with skimpier coverage, plan designs could potentially discriminate against people with pre-existing conditions. In addition, individuals who use services and benefits no longer included in the EHBs could face substantial increases in out-of-pocket costs. As such, the Council is recommending that our AMA oppose the removal of categories from the EHB package. In addition, the Council believes that our AMA should also oppose waivers of EHB requirements that lead to EHB categories and their associated protections against annual and lifetime limits, and out-of-pocket expenses, being eliminated.

In addition, after the expiration of the ACA's reinsurance program, and with policymakers and stakeholders evaluating various options to improve the stability of health insurance premiums and the overall health insurance marketplace, the Council reevaluated AMA policy with respect to how to best subsidize the costs of high-cost and high-risk patients, who may have pre-existing conditions. Critics of high-risk pools as a viable option for covering high-risk individuals have emphasized that the funding allocated to them, in the past and in legislation that was considered this year, has not been sufficient. More importantly, however, is that traditional high-risk pools have provided individuals with pre-existing conditions with second-class insurance, with waiting periods to get pre-existing conditions covered, higher premiums, potentially high deductibles, and lifetime limits on benefits. As such, the Council is recommending that Policy H-165.995 be rescinded, resulting from the evidence that shows the consequences of high-risk pools, and their subjection of individuals with pre-existing conditions to a different level of health insurance. At this juncture, considering the success of the ACA's reinsurance program, as well as state reinsurance programs, the Council believes that, considering finite resources, that resources should be directed to reinsurance programs. Reinsurance provides an equitable, fair and cost-effective mechanism to subsidize the costs of high-risk and high-cost patients, and protects patients with pre-existing conditions. The Council concludes that data suggest that a permanent reinsurance program may be a desirable policy option, whether administered at the federal or state level.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and the remainder of the report be filed:

1. That our American Medical Association (AMA) oppose the removal of categories from the essential health benefits (EHB) package and their associated protections against annual and lifetime limits, and out-of-pocket expenses. (New HOD Policy)

2. That our AMA oppose waivers of EHB requirements that lead to the elimination of EHB categories and their associated protections against annual and lifetime limits, and out-of-pocket expenses. (New HOD Policy)

3. That our AMA prefer reinsurance as a cost-effective and equitable mechanism to subsidize the costs of high-cost and high-risk patients. (New HOD Policy)

4. That AMA Policy H-165.995 be rescinded. (Rescind HOD Policy)

Fiscal Note: Less than $500.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 5-I-17

Subject: Reaffirmation of AMA Policy Opposing Caps on Federal Medicaid Funding (Council on Medical Service Report 9-A-17)

Presented by: Paul A. Wertsch, MD, Chair

Referred to: Reference Committee J (Peter C. Amadio, MD, Chair)

At the 2017 Annual Meeting, the House of Delegates referred Council on Medical Service Report 9-A-17, "Capping Federal Medicaid Funding." The report advocated for a series of safeguards in the event of federal Medicaid funding being capped. Debate on the report focused on an imminent Senate bill to undo the Medicaid expansion of the Affordable Care Act (ACA) and replace it with state per capita caps or block grants.

At the same meeting, the House of Delegates adopted Policy H-290.963, "Federal Medicaid Funding," which states that our American Medical Association (AMA): (1) opposes caps on federal Medicaid funding; and (2) advocates that Congress and the Department of Health and Human Services seek and take into consideration input from our AMA and interested state medical associations, national medical specialty societies, governors, Medicaid directors, mayors and other stakeholders, during the process of developing federal legislation, regulations, and guidelines on Medicaid funding.

BACKGROUND

Expanding Medicaid eligibility to most individuals with incomes up to 138 percent of the federal poverty level was a key strategy in expanding health insurance coverage under the ACA and accounted for 63 percent of coverage gains in 2014. Medicaid expansion resulted in an estimated 11 million newly enrolled beneficiaries in 2015. The program currently covers approximately 73 million beneficiaries nationwide. The Medicaid cap safeguards proposed in Council on Medical Service Report 9-A-17 included:

a. Individuals, including children and adolescents, who are currently eligible for Medicaid should not lose their coverage, and federal funding for the amount, duration, and scope of currently covered benefits should not be reduced;
b. The amount of federal funding available to states must be sufficient to ensure adequate access to all statutorily required services;
c. Cost savings mechanisms should not decrease patient access to quality care or physician payment;
d. The methodology for calculating the federal funding amount should take into consideration the state's ability to pay for health care services, rate of unemployment, concentration of low income individuals, population growth, and overall medical costs;
e. The federal funding amount should be based on the actual cost of health care services for each state;

f. The federal funding amount should continue to fund the Affordable Care Act (ACA) Medicaid expansion populations in states that have expanded Medicaid and provide non-expansion states with the option to expand Medicaid with additional funding to cover their expansion populations;
g. The federal funding amount should be indexed to accurately reflect changes in actual health care costs or state-specific trend rates, not on a preset growth index (e.g., consumer price index);
h. Maximum cost-sharing requirements should not exceed five percent of family income; and
i. The federal government should monitor the impact of capping federal Medicaid funding to ensure that patient access to care, physician payment and the ability of states to sustain their programs has not been compromised.

The House of Delegates had a robust discussion about the strategic AMA message that would be implied by adopting the proposed safeguards.

In 2017, Congress considered and defeated numerous proposals to repeal and replace the ACA, which included large (up to $880 billion) reductions to Medicaid and recommendations to cap federal Medicaid spending.

- In March 2017, the American Health Care Act was introduced in the US House of Representatives to repeal and replace the ACA, in part by discontinuing funding for the ACA Medicaid expansion and capping federal Medicaid funding to states.
- In June 2017, during the Annual Meeting of the House of Delegates, the Better Care Reconciliation Act was introduced in the Senate and included a large reduction in federal Medicaid spending, a return to categorical Medicaid eligibility, and a state option to receive a federal block grant for the ACA expansion population of nondisabled adults.
- In July 2017, the Senate considered a "skinny repeal" bill that left Medicaid intact.
- In September 2017, the Senate considered the Graham Cassidy measure, which would have terminated the ACA's Medicaid expansions, premium tax credits, cost-sharing reduction payments, and small business tax credits. It would also have imposed per capita caps on Medicaid funding and offered states the alternative of a broader Medicaid block grant.

DISCUSSION

At the time that this report was written, Congress had not taken up additional legislation to repeal and/or replace the ACA. The AMA opposed all of the noted bills and urged Congress to initiate a bipartisan effort to address shortcomings in the ACA. The Council believes the policy adopted at the 2017 Annual Meeting, which opposes caps on federal Medicaid funding, remains relevant and recommends its reaffirmation.

RECOMMENDATION

The Council on Medical Service recommends that the following be adopted in lieu of Council on Medical Service Report 9-A-17 and the remainder of the report be filed:

That our American Medical Association Policy H-290.963, "Federal Medicaid Funding," which opposes caps on federal Medicaid funding, be reaffirmed. (Reaffirm HOD Policy)

Fiscal Note: Less than $500.

JOINT REPORT OF THE COUNCIL ON MEDICAL SERVICE AND THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-17)
Payment and Coverage for Genetic/Genomic Precision Medicine
(Reference Committee J)

EXECUTIVE SUMMARY

The discovery of thousands of disease-related genes, aided by the mapping of the human genome, has led to medical innovations capable of dramatically improving patient-centered care and outcomes. Tens of thousands of genetic/genomic tests have been developed to screen for and diagnose diseases, tailor disease treatments, predict susceptibility to certain conditions, and inform prevention strategies. The number of targeted therapeutics capable of responding to particular genetic alterations has also increased exponentially, as have "companion diagnostics" tests that delineate which subpopulations will (or will not) benefit from particular therapeutics.

Precision medicine is a tailored approach to health care that accounts for individual variability in the genes, environment and lifestyle of each person. Physicians already practice precision medicine by managing each patient according to his or her unique symptoms, history, and preferences, but recent technological advances have vastly improved the ability to integrate genetic/genomic aspects of precision medicine into clinical practice. At the same time, new health care payment and delivery models are focused on value and require that health care services demonstrate their value to patients and the health care system as a prerequisite for payment and coverage.

Advanced bioinformatics programs are being used to generate scientific evidence of the validity of genetic/genomic tests and therapeutics and also increase understanding of many health conditions. Notably, there is considerable variability among public and private payers with regard to the evidentiary requirements for coverage of genetic/genomic precision medicine. Moreover, different insurers may review the same evidence yet reach conflicting conclusions about medical necessity and coverage of these services. The Councils initiated this joint report to provide an overview of genetic/genomic precision medicine and the current coverage and payment landscape; describe AMA policy and activity in this arena; and present policy recommendations that address inconsistencies in payment and coverage for genetic/genomic precision medicine services.

JOINT REPORT OF THE COUNCIL ON MEDICAL SERVICE
AND THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CMS/CSAPH Joint Report I-17

Subject: Payment and Coverage for Genetic/Genomic Precision Medicine

Presented by: Paul A. Wertsch, MD, Chair, Council on Medical Service
Robert Gilchick, MD, MPH, Chair, Council on Science and Public Health

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

The discovery of thousands of disease-associated genes, aided by the mapping of the human genome in 2003, has led to medical innovations capable of dramatically improving patient-centered care and outcomes. As of July 2017, the National Institutes of Health's Genetic Testing Registry (GTR®), which is a central location for voluntary submission of genetic information by providers, included information on more than 52,000 genetic/genomic tests for more than 10,000 conditions.[1] These genetic/genomic tests help screen for and diagnose diseases, tailor disease treatments, predict susceptibility to certain conditions, and inform prevention strategies. The number of targeted therapeutics capable of responding to particular genetic alterations has also increased exponentially, as have "companion diagnostics" tests that delineate which subpopulations will (or will not) benefit from particular therapeutics.

Precision medicine is a tailored approach to health care that accounts for individual variability in the genes, environment and lifestyle of each person. Physicians already practice "precision medicine" by managing each patient according to his or her unique symptoms, medical and family history, and preferences. However, recent technological advances such as the development of large-scale biologic databases (e.g., the human genome sequence), powerful methods for characterizing patients (e.g., proteomics, metabolomics, genomics, cellular assays, and mobile health technologies), and computational tools for analyzing large sets of data have vastly improved the ability to apply precision medicine principles to patient care. Precision medicine tests, technologies and therapeutics are increasingly being adopted into clinical practice as evidence of their effectiveness grows. At the same time, new health care payment and delivery models are focused on value and require that health care services demonstrate their value to patients and the health care system as a prerequisite for payment and coverage.

The Councils initiated this joint report to provide an overview of coverage and payment for genetic/genomic precision medicine; describe AMA policy and activity in this arena; and make policy recommendations. Genetic/genomic testing is used to analyze an individual's DNA and can confirm or rule out a suspected genetic condition or help determine an individual's chance of developing or passing on a genetic disorder. Environmental and behavioral data are also essential components of precision medicine, but unlike genetic/genomic data, their clinical use at this time is less common and coverage options are largely undeveloped. The term "genetic/genomic" is used throughout this report to refer to tests that analyze single genes or variants (genetic tests) as well as those that analyze larger portions of the genome, including multiple variants and/or genes, and whole exome and genome sequencing (genomic tests).

BACKGROUND

Precision medicine is routinely used in several specialties, most notably oncology. Using precision oncology, patients with certain cancers undergo testing that enables physicians to molecularly characterize their tumors, and tailor chemotherapy or other targeted therapeutics based on the genetic profile of their tumors. One common example is multi-variant panel tests that determine recurrence risk and potential response to chemotherapy in certain breast cancer patients. Outside of oncology, newborn screening, a state-based program in which every newborn is tested for dozens of genetic diseases that must be treated to avoid serious morbidity, is an example of precision medicine being applied on a large scale. Revolutionary advances in precision medicine have also enabled the diagnosis of rare and difficult-to-diagnose diseases, as well as the treatment of advanced-stage cancers and rare diseases that once were not treatable.

The potential exists for genetic/genomic precision medicine to be adopted more broadly into clinical practice because of advances in the technology used to collect and analyze huge sets of data, which has enabled enhanced research into genomic causes of disease and applications to clinical practice. The amount of data created with just one genome sequence is vast, and advanced bioinformatics programs are required to glean meaningful results from it. These data are being used to generate scientific evidence of the validity of genetic/genomic tests and therapeutics and also increase understanding of many health conditions. Despite these advances and initial evidence of improved health outcomes downstream, most patients do not have access to precision medicine because most public and private health insurers do not offer coverage for genetic/genomic services unless certain clinical criteria and evidentiary standards are met. As a result, access to this next generation of clinical testing services is often limited to individuals who can and choose to pay for it themselves, which has the potential to increase health disparities. While some consumers are paying for genetic tests on their own and without supervision of their physicians, many of these tests (often referred to as direct-to-consumer tests) have little clinical validity and may not be meaningful for physicians and patients. In April 2017, the Food and Drug Administration (FDA) approved marketing of certain direct-to-consumer genetic tests. Assuring the analytical and clinical validity of all clinical tests is critical to delivering optimal care to patients because not all tests are of the same quality and usefulness. Therefore, it is incumbent on physicians as well as payers to pay close attention to evaluations of the evidence supporting their clinical use.

PAYMENT AND COVERAGE

There is considerable variability among private and public payers with regard to the evidentiary requirements for coverage of genetic/genomic tests and services. Criteria used to evaluate tests and therapeutics generally include traditional measures such as analytical validity, clinical validity, and clinical utility. Analytical validity is the accuracy of the test in detecting the specific entity it was designed to detect without implying clinical significance such as diagnosis. Clinical validity is the accuracy with which a test identifies association of a specific entity (e.g., genetic variant) with a clinical purpose such as the presence, absence, predisposition to, or risk of a specific clinical condition. “Clinical utility” is a highly subjective term that does not have a universally accepted definition. Provider organizations, including national medical specialty societies, have defined this term to ensure that physicians are able to utilize testing when it is useful to physicians and patients by informing clinical care. Payers each define the term differently, with many adopting narrow definitions that require evidence of improved health outcomes downstream and that do not encompass the full value that a particular test or therapeutic may provide to patients, their families and society as a whole, such as establishing a diagnosis, reducing spending on continued diagnostic testing, and ending uncertainty for patients and their families. Clinical utility should refer to the

ability of a test to provide information related to the care of patients and to inform treatment decisions.

Currently, there is a well-established clinical evidence base to support coverage of a broad range of genetic/genomic tests; however, newer tests, which may be less expensive but for which the clinical evidence base has not yet matured, are rapidly and continuously becoming available. Because most insurers do not have the capability to assess the evidence for each test themselves they may require third-party health technology assessments (HTAs) which are then used in conjunction with other factors to make coverage determinations. HTA companies often look for evidence based on randomized controlled trials (RCTs)—which have historically been considered the gold standard for evidence generation—or comparable studies; however, the usefulness of many new genetic tests and therapeutics cannot feasibly be demonstrated using an RCT approach and may require novel research approaches. New genetic variants are being identified so rapidly that tests may need to be altered before RCTs can be completed. For example, variants that drive tumor growth and can potentially be targeted by a therapeutic are being identified and continually added to tumor testing panels. And for rare genetic diseases, RCTs may present ethical issues, take many years to complete, or never reach sufficient sample numbers.

HTAs may also require evidence not yet available that correlates genetic/genomic tests and therapies with clinical outcomes. A small study of private-payer challenges to establishing coverage of next-generation tumor sequencing (NGTS), which enables rapid examination of large numbers of genetic tumor alterations, found that most payers understand the potential benefits of NGTS.[2] However, a majority of payers interviewed for the study also reported that NGTS does not fit into their frameworks for medical necessity and does not meet their evidentiary standards requirements. For example, some NGTS tests identify variants for which a specific therapeutic does not yet exist or for which no clinical trials are underway. Despite the potential usefulness of knowing which variants are driving tumor growth for future clinical trials or new therapies, payers do not view such results as immediately actionable. Concerns among payers regarding implementation of NGTS and care delivery, such as the ability to effectively capture results in electronic health records and the preparedness of physicians to use the results in practice, are additional barriers to coverage.

Different types and levels of evidence are currently used to assess genetic/genomic tests, and some organizations—including the Agency for Healthcare Research and Quality, the American College of Medical Genetics and Genomics (ACMG), and the American Society of Clinical Oncology (ASCO)—evaluate available evidence and develop guidelines or recommendations for testing. AdvaMedDx—a trade association for diagnostics manufacturers—has developed a comprehensive framework for assessing the value of diagnostic tests and technologies based on four value drivers: clinical impact, non-clinical patient impact, care delivery revenue and cost impact, and population impact.

Medicare

Certain payers, including Palmetto GBA, a key Medicare contractor in the clinical testing domain, perform both a regulatory function—by requiring and assessing evidence of analytical/clinical validity—and a payer assessment of medical necessity. Medicare local coverage determinations (LCDs) regarding genetic/genomic tests have largely been developed by Palmetto GBA and then routinely adopted by other Medicare contractors in a process that has been lacking in transparency and sufficient stakeholder involvement to ensure that coverage decisions are in the best interests of patients. Several national medical specialty societies representing experts in molecular pathology have expressed serious concerns regarding the credibility of the evidence used by Palmetto GBA in

the drafting of LCDs that have denied coverage for certain genetic/genomic tests. Experts have stated that these LCDs lacked sufficient input, contradicted professional society practice guidelines, and encroached on physician clinical decision-making. As a result of the Palmetto GBA LCD process, the Centers for Medicare & Medicaid Services (CMS) does not cover many of the genetic/genomic tests that might be clinically meaningful to Medicare patients. According to the National Academies of Sciences, Engineering, and Medicine, as of April 2016, well over a thousand genetic tests had been excluded from Medicare coverage.[3]

Federal legislation (S. 794/H.R. 3635, "Local Coverage Determination Clarification Act") has been introduced to improve the LCD process and enable more patients to benefit from clinically validated medical innovations. This legislation would require Medicare contractors to establish a timely and open process for developing LCDs that includes open public meetings, meetings with stakeholders, an open comment period in the development of draft coverage policies, and a description of all evidence considered when drafting and finalizing coverage determinations. The LCD legislation would also require Medicare contractors seeking to adopt another contractor's proposal to independently evaluate the evidence needed to make a coverage determination, and would provide physicians and stakeholders a meaningful reconsideration process and options for appealing a Medicare contractor's decision to CMS. The AMA—along with the ACMG, ASCO, American Society for Radiation Oncology, American Society for Clinical Pathology, the Association for Molecular Pathology and the College of American Pathologists—supports the LCD legislation, which is consistent with AMA policy on LCDs.

Private Insurers

Private insurer coverage determination processes are neither transparent nor standardized across payers, and the evidence used by insurers to make coverage determinations regarding genetic/genomic tests and services can be inconsistent and convoluted. Just as coverage policies differ among insurers, their evidentiary standards requirements, interpretations of those standards, and evidence review processes vary as well. As a result, different insurers may review the same evidence of the validity and utility of a particular test or service yet reach conflicting conclusions about its medical necessity and coverage.

In addition to evidence-based evaluations of a genetic/genomic test's validity and utility, private payers often seek evidence of the service's cost-effectiveness, recommendations in professional society consensus statements or clinical practice guidelines, and peer-reviewed studies supporting its use.[4] One study examined private insurer coverage policies for cell-free DNA prenatal screening tests, which are routinely covered for high-risk pregnant women, to gain insights into payer decision-making for next-generation sequencing-based tests in general.[5] Most payers in this study used analytical and clinical validity and clinical utility to evaluate the evidence, and there was some variation in how they interpreted the evidence. This study also found that payers kept abreast of new peer-reviewed studies and professional society recommendations, and updated their coverage policies accordingly.[6]

Research into payer coverage of BRCA1/2 tests and gene panels has found that while nearly all payers covered BRCA1/2-only tests, gene panels that include BRCA1/2 were not likely to be covered because payers sought more evidence demonstrating the panels' clinical validity and clinical utility.[7] Gene panels identify more mutations than BRCA1/2-only tests but may also uncover incidental (or secondary) findings and variants of uncertain significance.[8] A study of payer-perceived challenges to covering hereditary cancer panels (HCPs) found that these panels may not be covered because they include variants or genes that have not been sufficiently studied and, as a consequence, the entire panel is considered investigational or experimental.[9] The study

highlights the complexity and uncertainty of the payment landscape by noting that while insurers generally do not cover HCPs, they may pay for them if, for example, they are billed for elements of the panel they considered medically necessary, or if payment denials are successfully appealed.[10] Payer policies may allow coverage of certain genetic/genomic tests and therapeutics under special circumstances or after successful appeal by physicians advocating on a patient's behalf. Physicians routinely advocate for patient access to testing that will inform diagnosis or management of disease, as well as patient access to therapeutics needed to treat disease; however, these efforts can be unduly burdensome.

On the front end, private insurers employ prior authorization, step therapy, and other forms of utilization management to control their members' access to certain services, including genetic/genomic testing and the treatments indicated by this testing. Utilization management requirements also involve very time-consuming processes that divert physician resources away from patient care. Prior authorization often interferes with patient care by either delaying that care or denying access to certain tests and therapeutics. Several large private insurers have established national prior authorization programs for genetic/genomic testing and will deny payment for services that have not been properly authorized or, in some cases, ordered by a geneticist or genetic counselor or carried out by insurer-approved laboratories. Some of these insurers have launched online, automated prior authorization programs for genetic/genomic testing. Certain insurers have instituted a stepwise approach to genetic/genomic testing, in which a less comprehensive test (assessing only one or a few variants or genes) must be ordered first and have inconclusive results before more comprehensive testing (sequencing of one or more entire genes or multiple variants) can be ordered. Insurers may also enforce limitations on the frequency of genetic testing, including sequencing, which is not appropriate in situations where test results may significantly change over time.

At least one large insurer requires physicians to use the insurer's own clinical decision support tool, which may not be compatible with physicians' EHRs and which may be viewed as potentially infringing on the clinical judgment of physicians. Certain national insurers have also instituted precertification requirements that require patients to receive pre-test genetic counseling from a board-certified genetic counselor or clinical geneticist before genetic tests can be ordered. These policies effectively reduce access to genetic testing for patients who do not have access to those professionals or are being treated by non-geneticist physicians who are fully capable of providing pre-test counseling. While AMA Policy H-480.944 supports genetic counseling, Policy H-460.902 opposes genetic testing restrictions based on specialty. A study of BRCA1/2 test cancellation rates during the periods before and after one national insurer began mandating pre-test counseling by genetic counselors or clinical geneticists found that the mandate significantly reduced patient access to testing.[11]

Cost-effectiveness

Health care costs continue to rise despite widespread efforts to insert value into models of care delivery and benefit design. Accordingly, cost-effectiveness, affordability, and value are critical to the Councils' discussion of precision medicine and the growing market of genetic/genomic tests and therapeutics. Although whole genome sequencing has become much more affordable than it once was, most multi-variant tests are expensive, ranging from $500 to $5000. Single gene tests may cost as low as about $100 for targeted mutation analysis (testing for one or a few variants in the gene) and approximately $500 for sequencing the entire gene.

For many genetic/genomic tests, there is widespread variability in the test's price as well as payment and coverage for that test, which must be sorted out by ordering physicians who must also

take into account patient cost-sharing expenses. In some cases, patients may request genetic/genomic testing that is not covered by insurance and is instead purchased directly from a test company at an entirely different price. Cost comparison tools (e.g., Fair Health) can be used by patients and physicians to estimate the costs of some genetic tests and services.

More research is needed to demonstrate the cost-effectiveness and economic value of precision medicine. A 2014 study concluded that many genetic tests are cost-effective but fewer are cost saving. Notably, a large number of available tests have not yet been evaluated.[12] A systematic review of economic evaluations of genetic and pharmacogenetics tests found that only 21 percent of pharmacogenetics tests and 12 percent of predictive genetic tests are cost saving. Reporting of incidental/secondary findings using sequencing technologies has been found to be cost-effective in certain circumstances but not necessarily cost saving in healthy populations unless the cost of the sequencing is below a certain threshold.[13,14]

Genetic Discrimination and Privacy

In 2008, after 13 years of effort on the part of many advocacy organizations including the AMA, Congress passed the Genetic Information Nondiscrimination Act (GINA) nearly unanimously. Title I of GINA prohibits group and individual health insurers from using a person's genetic information in determining eligibility or premiums and prohibits health insurers from requesting or requiring that a person undergo a genetic test in order to collect genetic information on that person for underwriting decisions. Importantly, GINA does not prohibit health insurance underwriting based on current health status, including manifest disease of a genetic nature. Rather, it is intended to protect individuals with a genetic predisposition to disease that has not manifested, whether or not an individual has knowledge about that predisposition based on his or her own genetic test results or the genetic test results or manifestation of disease in a family member. Since the enactment of GINA, only a modest number of genetic discrimination complaints have been filed under its provisions; in 2016, 238 cases of genetic discrimination were filed out of nearly 100,000 total discrimination cases filed.[15] It is possible that the small number of cases reflects the effectiveness of GINA at discouraging the practice of discrimination on the basis of genetics by health insurers, or alternatively, that discrimination is occurring but is unrecognized or unreported.

Fears about genetic discrimination have led to refusal by some to undergo genetic testing.[16,17,18] This can have serious health implications for individuals for whom genetic testing would be beneficial. Even among those who do undergo genetic testing, many withhold test results from their physicians, and some request that their results be placed in a "shadow chart" or withheld entirely from their medical record. Information that is not available to physicians can have detrimental effects on patient care because treating physicians unfamiliar with the patient will have no knowledge of genetic test results unless that information is volunteered by the patient. With more frequent use of technologies that involve analysis of patients' genomic information, the potential for misuse and discrimination grows. A very important additional consideration is how difficult it has become to maintain the privacy and security of genomic information. In October 2012, the Presidential Commission for the Study of Bioethical Issues concluded that efforts to de-identify genetic information are exceptionally challenging and will gradually become impossible.[19] In January 2013, a group of scientists demonstrated that the genetic information provided by individuals who had been assured anonymity could in fact be re-identified.[20,21,22] Therefore, given the rapid uptake of genomic-based technologies in both the clinical setting and outside the clinic, there is a pressing need to remain vigilant on policies that protect the privacy of individuals' genetic information.

Physician Education

Educating physicians about precision medicine, including genetic/genomic testing and therapeutics, presents its own unique challenges, given the rapid pace of discoveries as well as extensively documented physician time constraints. Physicians must have the knowledge and skills to integrate precision medicine into their clinical practice for obvious reasons related to professionalism and patient care, and also to effectively advocate for insurer coverage of valid and meaningful genetic/genomic tests and targeted therapeutics. From a payment perspective, physicians will likely need more time for counseling patients and to analyze and explain genetic test results, and they should be adequately paid for these services. Patients who have paid for direct-to-consumer testing may also present genetic risk factor findings to their physicians, who are then challenged to consider how to explain the test results and also justify payment for clinical follow-up. Additionally, laboratories providing the tests are increasingly requesting large quantities of documentation from physicians that are needed for retrospective reviews.

The technical complexity of precision medicine adds to the hurdles faced by physicians interested in integrating this type of care into their practices. Training and implementation costs associated with adopting new care practices must be taken into consideration. As in many areas of medicine, there is also the need for significant health information technology (health IT) improvements that will enable interoperability, access, and clinical decision support while not creating additional burdens and usability challenges for physicians.

AMA ACTIVITY

In recent years, the AMA House of Delegates has established relevant policies recommended by the councils. The Council on Science and Public Health (CSAPH) has addressed several topics related to precision medicine including genome editing (CSAPH Report 3-I-16), genomics in hypertension (CSAPH Report 1-I-14), genomics in type 2 diabetes (CSAPH Report 2-A-14), genetic discrimination (CSAPH Report 7-A-13), and next-generation genomic sequencing (CSAPH Report 4-I-12). CSAPH Report 3-A-16 discusses the Precision Medicine Initiative (PMI), now called the All of Us initiative, which is creating a research cohort of over one million volunteers who will share their genetic, environmental and lifestyle data.

The Council on Medical Service developed Report 2-A-13 on value-based insurance design; Report 7-A-14 on coverage and payment for telemedicine; Report 5-I-16 on incorporating value into pharmaceutical pricing; and Report 6-I-16 on integrating mobile health applications and devices into clinical practice.

Regulatory Activity

Uncertainties in the oversight and regulation of genetic/genomic testing services have the potential to stifle innovation and impede patient access to what could be transformative, life-altering care. The AMA, in collaboration with several national medical specialty societies, has developed legislative principles (https://www.ama-assn.org/sites/default/files/media-browser/public/genetics/personalized-medicine-guiding-principles.pdf) to guide its advocacy efforts in this arena. The principles make clear that payment and coverage policies should not dictate which diagnostic or treatment options are available to physicians and patients, and should take into account the role of physicians in driving and applying genetic/genomic innovations. Furthermore, the principles reinforce that testing alone will not dictate treatment. Rather, physicians' diagnostic impressions and their interpretation of test results in the context of the patient's clinical situation and preferences should guide treatment options. Since regulation of

genetic tests is integral to physician practice and patient care, the AMA is engaged in ongoing advocacy with policymakers and other stakeholders to preserve the physician's role in all aspects of patient care, including the oversight of laboratory-developed tests and other components of precision medicine.

The AMA actively supports a Clinical Laboratory Improvement Amendments (CLIA)-based laboratory oversight system along with appropriate third-party accreditation, and is opposed to FDA oversight of laboratory-developed testing services in all but the most narrow of circumstances. Accordingly, the AMA has made public comments and statements opposing FDA oversight activities that infringe on the practice of medicine, and is engaged with a broad group of stakeholders to support regulatory reform for genetic tests that promotes innovation and preserves patient access. The AMA has also urged Congress to pursue modernization of the CLIA oversight framework for high complexity laboratory testing services that would establish standards for clinical validity and strengthen established standards related to quality control and quality assurance, and to personnel standards including regular proficiency testing. Strengthening the existing CLIA oversight framework will assure patient safety and provide a stronger structure to prevent laboratory errors while preserving patient access to care.

Protecting Access to Medicare Act (PAMA)

Section 216 of the Protecting Access to Medicare Act (PAMA), which was enacted in 2014, significantly revised the Medicare payment system for clinical tests by requiring that Medicare payment for laboratories be based on the weighted median of private payer rates. Regulations issued by CMS in June 2016 required laboratories that provide clinical testing, including certain physician office-based laboratories, to collect and report private payer payment and test volume data to CMS. CMS is using this private payer data to set new payment rates that will become effective on January 1, 2018.

The AMA has urged CMS to implement a number of measures to ensure the accuracy of the new payment rates, which will be based on a retrospective reporting period for data collection from 2016. The AMA has expressed serious concerns to CMS regarding the integrity of the data that will be used to calculate the new payment rates, and whether the rates will accurately reflect the weighted median of private payer payments, as Congress intended. Based on the lack of data integrity, the AMA and other stakeholders anticipate that the new payment rates could effectively reduce patient access to clinical lab testing. The AMA also continues to urge CMS to ensure that implementation of the new payment rates results in as little administrative burden for physicians as possible.

PAMA regulations also required CMS to issue Healthcare Common Procedure Coding System (HCPCS) codes to identify new advanced diagnostic laboratory tests (ADLTs), and clinical tests that are cleared or approved by the FDA (referred to as Clinical Diagnostic Laboratory Tests, or CDLTs), if an applicable Current Procedural Terminology (CPT) code (HCPCS level I) does not exist; and to provide, upon request, either a HCPCS code or unique identifier for test tracking and monitoring. In order to address these coding provisions, the CPT Editorial Panel approved in November 2015, and finalized at its February 2016 panel meeting, the new Proprietary Laboratory Analyses (PLA) section of the CPT code set. PLA codes include a descriptor for laboratories or manufacturers that want to more specifically identify their tests. An important part of the development of this new set of codes is that industry and other stakeholders, including subject matter experts, actively participate in the PLA process. To that end, the Panel created the Proprietary Laboratory Analyses Technical Advisory Group (PLA-TAG) to advise the Panel on applications received for codes to be added to the PLA section of CPT. Along with representation

by the Panel and certain Panel workgroups, the PLA-TAG is composed of individuals with expertise relating to the services covered under the CPT PLA section. These include, but are not limited to, members from various industry segments such as independent laboratories, private payers, professional/industry organizations, commercial laboratories, academic medical institutions and private practitioners. Members of the PLA-TAG will play a crucial role in the PLA code creation process by reviewing CPT PLA code change applications and making recommendations regarding these requests for CPT codes that describe ADLTs or CDLTs.

Prior Authorization

Due to its widespread usage and the significant administrative and clinical concerns it can present, the AMA addresses prior authorization through a multifaceted approach that includes a number of high-profile activities, including the release of Prior Authorization and Utilization Management Reform Principles to address priority concerns. The principles were developed by a workgroup of state and national medical specialty societies, national provider associations and patient representatives convened by the AMA. The 21 principles (https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf) seek to improve prior authorization and utilization management programs by addressing broad categories of concern including: clinical validity; continuity of care; transparency and fairness; timely access and administrative efficiency; and alternatives and exemptions. Health plans, benefit managers and any other parties conducting utilization management, as well as accreditation organizations, have been urged to apply the principles to both medical and pharmacy benefits. The principles, which have gained widespread support since their release, with over 100 stakeholder organizations signing on in support of their objectives, include the following:

- Any utilization management program applied to a service, device or drug should be based on accurate and up-to-date clinical criteria and never cost alone. The referenced clinical information should be readily available to the prescribing/ordering provider and the public.
- Utilization management programs should allow for flexibility, including the timely overriding of step therapy requirements and appeal of prior authorization denials.
- Utilization review entities should offer an appeals system for their utilization management programs that allows a prescribing/ordering provider direct access to a provider of the same training and specialty/subspecialty for discussion of medical necessity.

The AMA has also engaged in two research projects to gather data on the impact of prior authorization on patients and physician practices. A web-based survey of 1000 practicing physicians conducted with a market research partner in December 2016 found that practices complete an average of 37 prior authorizations per physician per week, which take the physician and his/her staff an average of 16 hours—the equivalent of two business days—to process. Ninety percent of physicians reported that prior authorization delays patients' access to necessary care. The survey results (https://www.ama-assn.org/sites/default/files/media-browser/public/government/advocacy/2016-pa-survey-results.pdf) serve as a valuable framework for the aforementioned principles and have provided a strong evidence base for AMA advocacy efforts related to prior authorization. The AMA is also partnering on an academic research project seeking to measure the overall impact of prior authorization on health care costs and outcomes.

The AMA also works closely with state medical associations and national medical specialty societies to address prior authorization and other utilization management issues through state legislation. Several bills passed by state legislatures have been based on the AMA's model legislation, the "Ensuring Transparency in Prior Authorization Act" (https://www.ama-assn.org/sites/default/files/media-browser/specialty%20group/arc/model-bill-ensuring-

transparency-in-prior-authorization.pdf). The AMA's Prior Authorization Toolkit (https://www.ama-assn.org/system/files/media-browser/premium/psa/prior-authorization-toolkit_0.pdf) provides a useful overview of the current prior authorization landscape and tips for reducing practice burdens related to prior authorization, including implementation of standard electronic processes. In sum, prior authorization and other utilization management programs are high-priority targets for the AMA.

Educating Physicians

The AMA recognizes the importance of educating physicians and physicians-in-training about the clinical uses and ethical considerations of genetic/genomic services. To assist physicians who are encountering new precision medicine technologies, the AMA has partnered with Scripps Translational Science Institute and The Jackson Laboratory to develop "Precision Medicine for Your Practice" (http://education.ama-assn.org/precision-medicine.html), a series of short, online continuing medical educational modules covering specific topics in genomics and precision medicine, including expanded carrier screening in prenatal care, prenatal cell-free DNA screening, somatic cancer panel testing, large scale sequencing in the healthy individual, large scale sequencing as a diagnostic tool, and pharmacogenomics. In the near future, the AMA will be adding modules on sequencing the healthy individual, pharmacogenomics and neurogenomics.

Additionally, the AMA is carrying out research to identify physicians' educational and resource needs for appropriate implementation of precision medicine into practice. The AMA will continue to develop tools to assist physicians with precision medicine needs.

AMA and All of Us Initiative

As part of its pledge to assist with the PMI, which includes the All of Us Research Program, the AMA is committed to actively working to improve patient access to personal medical information and helping physicians leverage electronic tools to make health information more readily available; developing and disseminating resources including toolkits, podcasts and fact sheets; and improving awareness of the PMI/All of Us Initiative, and how to enroll in its cohort, among physicians.

Health IT and Digital Health

Significant improvements in EHR and other health IT capabilities are critically needed for precision medicine to reach its potential. Robust and interoperable health IT systems must be able to access and display longitudinal health data from each patient regardless of where the data is stored. EHRs are rich with biological, behavioral and environmental data; however, impediments to accessing and enabling the secure exchange of data across health care systems must be overcome. Clinical decision support that will enable application of the data to care management is also an essential component; however, many EHR systems in use today do not have such capabilities, and physicians are frustrated with the usability of EHR systems and report that they sometimes hamper safe and effective care. The AMA actively promotes EHRs that can provide clinical decision support and use genetic/genomic data to provide clinically meaningful information to physicians.

Beyond EHRs, the AMA is committed to understanding and influencing the evolution of health IT and digital health, both of which are integral to the implementation of precision medicine. The AMA provides leadership on digital solutions involving telemedicine and telehealth, mobile health, wearables, and remote monitoring. Using the expertise of physicians and input from partners on the leading edge of health technology, the AMA has developed resources, toolkits and training to help physicians navigate and maximize technology for improved patient care.

AMA POLICY

Policy H-460.908 acknowledges the increasingly important role of genomic-based personalized medicine applications in the delivery of care; calls for the development of educational resources and tools to assist in the clinical implementation of genomic-based personalized medicine; and directs the AMA to continue to represent physicians' voices and interests in national policy discussions of issues pertaining to the clinical implementation of genomic-based personalized medicine, such as genetic test regulation, clinical validity and utility evidence development, insurance coverage of genetic services, direct-to-consumer genetic testing, and privacy of genetic information. Policy D-460.968 supports the AMA's work with the PMI and also advocates for improvements to electronic health record systems that will enable interoperability and access without creating additional burdens and usability challenges for physicians.

Policy D-460.976 directs the AMA to maintain a visible presence in genetics and molecular medicine. Policy H-480.944 supports appropriate use of genetic testing, pre- and post-test counseling for patients undergoing testing, and physician preparedness in counseling patients or referring them to qualified genetics specialists, as well as the development of best practice standards concerning pre- and post-test genetic counseling. Under Policy H-460.902, the AMA opposes limiting the ordering of genetic testing based solely on physician specialty. The clinical application of next generation genomic sequencing is addressed by Policy H-460.905, while genome analysis and variant identification is the subject of Policy D-460.971. Policy D-480.987 focuses on direct-to-consumer marketing and availability of genetic tests, and recommends that genetic testing be carried out under the supervision of a qualified health professional. Policy H-65.969 strongly opposes discrimination based on genetic information.

Policy H-185.939 supports flexibility in the design and implementation of value-based insurance design (VBID), which explicitly considers the clinical value of a given service or treatment when determining cost-sharing structures or other benefit design elements. Policy H-185.939 calls for active involvement of practicing physicians; the use of high-quality, evidence-based data; and transparency of the methodology and criteria used to determine high- or low-value services or treatments and coverage and cost-sharing policies. The policy states that VBID should not restrict access to patient care and must include an appeals process to enable patients to secure care recommended by their physicians. The policy also calls for plan sponsors to engage in ongoing evaluation of the plan designs to ensure VBID coverage rules are updated in accordance with evolving clinical evidence.

AMA policy promotes price transparency and education regarding cost-sharing by health plans (Policies D-155.987 and H-165.828). Policy H-320.949 states that utilization management criteria should be based on sound clinical evidence, permit variation to account for individual patient differences, and allow physicians to appeal decisions. Policy D-330.908 advocates for improvements in the LCD process, including increased transparency and a prohibition on Medicare contractors adopting another contractor's LCD without a full and independent review. Policy D-330.918 directs the AMA to work with national medical specialty societies and CMS to identify outdated coverage decisions that create obstacles to clinically appropriate patient care. Policy H-460.909 outlines principles for comparative effectiveness research, and Policy D-390.961 advocates for adequate investment in this type of research and also better methods of data collection, development, reporting and dissemination of practical clinical decision-making tools. Policy H-155.960 promotes value-based decision-making, collection of clinical and cost data, and cost-effectiveness research, while principles to guide value-based decision-making are delineated in Policy H-450.938.

DISCUSSION

The Councils' work on precision medicine is timely given passage of the *21st Century Cures Act* and continued funding of the PMI, including the All of Us Research Program, and the Cancer Moonshot. The speed and volume of advances in genetics and genomics are impacting an array of regulatory, coding and payment processes that remain very fluid and will continue to be closely monitored by the AMA so that the physician perspective is clearly articulated. As with past health care innovations, the initial period of implementation of genetic/genomic precision medicine is complex and costly. Payers, policymakers and other stakeholders are challenged to keep up with the rapid development of new tests and technologies and the generation of evidence supporting their use, which are essential to ensuring patient safety while also preventing delays in payment and coverage for valid and meaningful services. In the long run, the Councils anticipate that genetic/genomic precision medicine services will become more affordable and in the mainstream across a variety of medical specialties.

The Councils' recommendations build upon existing AMA policy to establish new, foundational policy addressing the inconsistencies in payment and coverage of genetic/genomic precision medicine services. The Councils recommend reaffirmation of seven integral policies: Policy H-460.968, which directs the AMA's work on the PMI; Policy H-460.908, which directs the AMA to continue engaging in policy discussions related to the clinical implementation of genetics/genomics; Policy D-480.987, which focuses on direct-to-consumer marketing and availability of genetic testing; Policy H-185.939, which supports implementation of value-based insurance design, consistent with a series of principles regarding the clinical value of treatments and services; Policy H-329.949, which focuses on utilization management-related barriers to care; Policy H-65.969, which opposes discrimination based on genetic information; and Policy H-460.902, which opposes limitations by payers on the ordering of genetic testing based solely on physician specialty.

The Councils discussed the importance of sharing genomic variant data and ensuring that patients and physicians are notified of clinical significance changes. The Councils recommend adding a third clause to Policy D-460.971, which would encourage laboratories to establish a process by which patients and their physicians could be notified when interpretation and clinical significance changes for previously reported variants.

The Councils are concerned by the lack of transparency and standardization across payer coverage determination processes, which may hinder access to valid and meaningful tests and therapeutics as well as future innovations. Accordingly, the Councils recommend that the AMA encourage public and private payers to adopt processes and methodologies for determining coverage and payment for genetic/genomic precision medicine that promote transparency and clarity; involve stakeholders across disciplines, including genetic/genomic medicine experts; describe the evidence being considered and methods for updating the evidence; provide opportunities for comment and meaningful reconsiderations; and incorporate value assessments that consider the value of genetic/genomic tests and therapeutics to patients, families and society as a whole.

The Councils further recognize that the usefulness of many new genetic tests and therapeutics cannot feasibly be demonstrated using an RCT approach and will require novel research approaches. Accordingly, the Councils recommend that the AMA encourage coverage and payment policies for genetic/genomic precision medicine that are evidence-based and take into account the unique challenges of traditional evidence development through RCTs, and work with test developers to establish clear thresholds for acceptable evidence for coverage.

Because patient access to genetic/genomic precision medicine services is largely dependent on public and private insurer decisions to pay for them, the Councils recommend that the AMA work with national medical specialty societies and other stakeholders to encourage the development of a comprehensive payment strategy that facilitates more consistent coverage of genetic/genomic tests and therapeutics.

As additional steps toward timely and appropriate application of precision medicine into practice, the Councils recommend that the AMA encourage national medical specialty societies to develop clinical practice guidelines incorporating precision medicine approaches that support adoption of appropriate, evidence-based services; and support continued research and evidence generation demonstrating the validity, meaningfulness, cost-effectiveness and value of precision medicine.

Finally, the Councils recognize that the payment and coverage landscape for precision medicine is evolving, and emphasize that the Councils' work is ongoing. Future studies may be warranted by further innovation and as new technologies—such as artificial intelligence—are adopted into clinical practice.

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-460.968, which directs the AMA to work with the Precision Medicine Initiative, develop resources for physicians on this initiative, and continue to advocate for improvements to electronic health record systems that will enable interoperability and access while not creating additional burdens and usability challenges for physicians. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy H-460.908, which directs our AMA to continue representing physicians in policy discussions of issues related to the clinical implementation of genomic-based medicine, such as genetic test regulation, clinical validity and utility evidence development, insurance coverage of genetic services, direct-to-consumer genetic testing, and privacy of genetic information. (Reaffirm HOD Policy)

3. That our AMA reaffirm Policy D-480.987, which recommends that genetic testing be carried out under the supervision of a qualified health professional; encourages individuals interested in obtaining genetic testing to contact a qualified health professional; and directs the AMA to educate and inform physicians on the types of genetic tests available directly to consumers. (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-185.939, which supports flexibility in the design and implementation of value-based insurance design programs consistent with a series of principles regarding the clinical value of treatments and services. (Reaffirm HOD Policy)

5. That our AMA reaffirm Policy H-329.949, which states that utilization management criteria should be based on sound clinical evidence, permit variation to account for individual patient differences, and allow physicians to appeal decisions. (Reaffirm HOD Policy)

6. That our AMA reaffirm Policy H-65.969, which strongly opposes discrimination based on an individual's genetic information; support legislation that protects against genetic discrimination and misuse of genetic information; and supports education for health care providers and

patients on the protections against genetic discrimination currently afforded by federal and state laws. (Reaffirm HOD Policy)

7. That our AMA reaffirm Policy H-460.902, which opposes limitations by public and private payers on the ordering of genetic testing that are based solely on physician specialty. (Reaffirm HOD Policy)

8. That our AMA modify Policy D-460.971 by addition and deletion to read as follows:

   Our AMA: (1) encourages payers, regulators and providers to make clinical variant data and their interpretation publicly available through a system that assures patient and provider privacy protection; ~~and~~ (2) encourages laboratories to place all clinical variants and the clinical data that was used to assess the clinical significance of these results, into the public domain which would allow appropriate interpretation and surveillance for these variations that can impact the public's health~~.~~; and (3) encourages laboratories to establish a process by which patients and their physicians could be notified when interpretation and clinical significance changes for previously reported variants. (Modify Current HOD Policy)

9. That our AMA encourage public and private payers to adopt processes and methodologies for determining coverage and payment for genetic/genomic precision medicine that:
   a. Promote transparency and clarity;
   b. Involve multidisciplinary stakeholders, including genetic/genomic medicine experts and relevant national medical specialty societies;
   c. Describe the evidence being considered and methods for updating the evidence;
   d. Provide opportunities for comment and review as well as meaningful reconsiderations; and
   e. Incorporate value assessments that consider the value of genetic/genomic tests and therapeutics to patients, families and society as a whole, including the impact on quality of life and survival. (New HOD Policy)

10. That our AMA encourage coverage and payment policies for genetic/genomic precision medicine that are evidence-based and take into account the unique challenges of traditional evidence development through randomized controlled trials, and work with test developers and appropriate clinical experts to establish clear thresholds for acceptable evidence for coverage. (New HOD Policy)

11. That our AMA work with interested national medical specialty societies and other stakeholders to encourage the development of a comprehensive payment strategy that facilitates more consistent coverage of genetic/genomic tests and therapeutics. (New HOD Policy)

12. That our AMA encourage national medical specialty societies to develop clinical practice guidelines incorporating precision medicine approaches that support adoption of appropriate, evidence-based services. (New HOD Policy)

13. That our AMA support continued research and evidence generation demonstrating the validity, meaningfulness, short-term and long-term cost-effectiveness and value of precision medicine. (New HOD Policy)

Fiscal Note: Less than $500

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 801
(I-17)

Introduced by: Idaho, Montana, Nevada, New Mexico, North Dakota, Wyoming, Utah

Subject: Chronic Care Management Payment for Patients Also on Home Health

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, The Centers for Medicare and Medicaid Services (CMS) may reimburse physicians for Chronic Care Management (CCM) services to manage patients with two or more chronic conditions, meeting requirements outlined in Medicare regulations; and

Whereas, When patients are enrolled in home health episodes, physicians in Rural Health Clinics (RHCs) or Federally Qualified Health Centers (FQHCs) are unable to receive CCM reimbursement for treatment or supervision of a patient with chronic conditions under the CCM or home health supervision codes; and

Whereas, Most physicians can receive reimbursement for another service when providing home health supervision, except physicians in RHCs or FQHCs that are unable to receive reimbursement for home healthcare supervision code G0181 (*Physician supervision of a patient receiving Medicare covered services provided by a participating home health agency requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans*); and

Whereas, For RHCs or FQHCs to provide integrated healthcare as Patient-Centered Medical Homes (PCMH) and provide patients with better health and lower healthcare costs, allowing CCM reimbursement to patients in a current home health episode would align with CMS regulations for CCM; therefore be it

RESOLVED, That our American Medical Association advocate for the authorization of Chronic Care Management (CCM) reimbursement for Rural Health Clinics, Federally Qualified Health Centers, and all other physician clinics providing CCM for patients enrolled in a home health episode, to the Centers for Medicare and Medicaid Services and to Congress if federal law must be amended. (New HOD Policy)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 09/19/17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 802
(I-17)

Introduced by: Medical Student Section

Subject: Opposition to Medicaid Work Requirements

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, An estimated 1.75 million full-time students are currently enrolled in the Medicaid program and are not working;[1] and

Whereas, Several states are in the process of or have formally submitted Section 1115 state waiver requests to include work requirements for Medicaid eligibility;[2] and

Whereas, The Centers for Medicare and Medicaid Services indicated support for Section 1115 state waiver initiatives involving "training, employment and independence";[3] and

Whereas, Studies have found that Medicaid expansion has had a positive or neutral effect on employment and the labor market;[4,5]and

Whereas, Implementation of work requirements would expand the administrative cost of the Medicaid program per enrollee for states while only having a modest benefit to employment that decreases over time when implemented in other programs;[2,6,7,8]and

Whereas, An estimated 3.43 million non-Supplemental Security Income Medicaid recipients report being too sick to work in addition to 2.74 million non-SSI Medicaid recipients report they couldn't work because of taking care of their home or family;[1] and

Whereas, A work requirement as a criterion for Medicaid eligibility could bar access to healthcare from vulnerable people too sick to work, acting as caregivers, or unable to find employment;[1] therefore be it

RESOLVED, That our American Medical Association oppose work requirements as a criterion for Medicaid eligibility. (New HOD Policy)

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Fiscal Note: Modest - between $1,000 - $5,000.

Received: 09/20/17

RELEVANT AMA POLICY

Proposed Revisions to AMA Policy on Medical Student Debt H-305.928
Medicaid Expansion Options and Alternatives H-290.966
Medicaid - Towards Reforming the Program H-290.997
Giving States New Options to Improve Coverage for the Poor D-165.966
Medicaid Expansion D-290.979
Affordable Care Act Medicaid Expansion H-290.965

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 803
(I-17)

Introduced by: Medical Student Section

Subject: Air Ambulance Regulations and Reimbursements

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, Air ambulances requested by third-party medical professionals or first responders[1] improve access to level 1 trauma centers for 87 million Americans who would not be able to receive emergent care in a timely manner otherwise, with 86.4% of the U.S. population living within a 15-to-20-minute response area of an air ambulance;[1] and

Whereas, Fifty-nine percent of patients transported by air ambulance had minor injuries, as defined by an Injury Severity Score of less than 15;[2] and

Whereas, The Airline Deregulation Act of 1978 prohibits states from regulating the price, route, or service of an air carrier, including air ambulances, for the purposes of increasing competition, reducing rates, and improving airline passenger service; however, since Medicare's creation of a national fee schedule for air ambulances in 2002, more than half of the air ambulance industry is controlled by 4 for-profit operators, with an increase in the number of air ambulances from 545 in 2002 to 1,045 in 2015;[3,4,5] and

Whereas, Air Methods, the nation's largest air ambulance operator, has seen an increase in their average bill of $17,262 in 2009 to $50,199 in 2016, far more than the actual cost for a flight of only $10,199;[1,4] and

Whereas, Lawsuits to collect payment from patients for use of medical helicopters are on the rise;[6] and

Whereas, Medicare only reimburses 59% of air ambulance costs, adding an average of $15,984 to the cost of self-pay or privately insured patients as air ambulance operators recoup what they lose on below-cost transports funded by the government;[1] and

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Whereas, Private insurance companies that offer ambulance coverage only cover an average of 36.5% of the air ambulance's bill and, unlike Medicare and Medicaid, there are no regulations preventing them from balance billing patients for charges after coverage has been applied;[7,8] and

Whereas, Between 2013 and 2016, insurance departments from nine states reviewed 55 incidences in which consumers complained of $3.8 million in combined charges, an average charge of $70,000 per trip;[9] and

Whereas, Laws from Wyoming seeking to cap air ambulance fees and North Dakota forcing air ambulance companies to become participating providers by joining major insurance company networks have been struck down in federal courts;[10] and

Whereas, The AMA supports the education of physicians and the public about the costs associated with inappropriate use of emergency patient transportation systems (AMA Policy H-130.954); therefore be it

RESOLVED, That our American Medical Association and appropriate stakeholders study the role, clinical efficacy, and cost-effectiveness of air ambulance services, including barriers to adequate competition, reimbursement, and quality improvement. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 09/20/17

RELEVANT AMA POLICY

Non-Emergency Patient Transportation Systems H-130.954
The AMA: (1) supports the education of physicians and the public about the costs associated with inappropriate use of emergency patient transportation systems; and (2) encourages the development of non-emergency patient transportation systems that are affordable to the patient, thereby ensuring cost effective and accessible health care for all patients.
Sub. Res. 812, I-93 Reaffirmed: CMS Rep. 10, A-03 Reaffirmed in lieu of Res. 101, A-12

See also:
H-45.986 Protection of Insurance Coverage for Medical Attendants Aboard Non-Scheduled Aircraft
H-240.978 Medicare's Ambulance Service Regulations
H-215.973 Emergent Care Adjacent to Hospitals

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[8] New Mexico, Office of Superintendent of Insurance. Air Ambulance Memorial: Study Report. January 2017. http://www.osi.state.nm.us/MiscPages/docs/newsroom/Air%20Ambulance%20Memorial%20-%201.19.17.pdf
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[10] Neary, B. Wyoming seeks to block judge's order on air ambulance fees. *Associated Press*. August 2016

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 804
(I-17)

Introduced by: Indiana

Subject: Prior Authorization

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, The cost of health care is ever-increasing; and

Whereas, Employers and other payers are incessantly looking for ways to evaluate the use of certain high-cost medications and services; and

Whereas, One way to do that is to require prior authorization for more and more services; and

Whereas, The additional work required by physician offices has exponentially increased, as witnessed by the need for clinical practices to hire additional employees who spend their total day requesting and arguing for care and services deemed appropriate by the attending physician; and

Whereas, On May 22, 2014, the Centers for Medicare & Medicaid Services released a proposed rule to establish a prior authorization process, endorsing that this would ensure Medicare beneficiaries receive medically necessary care while minimizing the risk of improper payments and therefore protecting the Medicare Trust Fund; and

Whereas, This prior authorization process has been difficult to manage, and has been a significant drain on provider resources--especially at the beginning of each calendar year; and

Whereas, Long-term, effective clinical treatments are frequently required to be re-authorized at the beginning of each calendar year or with any third-party payer change, and often denied with suggestions to take steps backward to previously tried and failed treatments; and

Whereas, This prior authorization process may have worked with some limited cases, but overall, it increases provider burden, complicates patient care and has the potential to cause clinical relapses and worsening medical conditions, which are well-understood by the attending doctor; and

Whereas, Websites with lists of approvable, preferred or otherwise acceptable care and services are neither consistent nor transparent; therefore be it

RESOLVED, That our American Medical Association promote the appropriate use of prior authorization primarily for initial requests and services that fall outside the standard of care (Directive to Take Action); and be it further

RESOLVED, That our AMA implement and promote policy that minimizes the need for prior authorization annually or on any other schedule when the request is for continuity of care and the prior authorization is for regimens that are working well to control a patient's condition (Directive to Take Action); and be it further

RESOLVED, That our AMA create a policy that prior authorizations need to be completed within three working days by the health plan or pharmacy if approved, or if the prior authorization is denied, the denial must include an explanation, unique and specific to the individual patient, and, if no answer is obtained within three days, the prior authorization is deemed approved and patient care may proceed (New HOD Policy); and be it further

RESOLVED, That our AMA create a policy for the prior authorization process that, unless a health plan, pharmacy vendor or other payer source can document that medical care or a specific service or pharmaceutical is NOT appropriate or medically-indicated based on nationally recognized evidence-based guidelines, the health plan, pharmacy vendor or other payer source shall approve the request of the attending physician (New HOD Policy); and be it further

RESOLVED, That our AMA schedule quarterly meetings with insurance companies to discuss any prior authorization issues, as well as any other matters pertinent to physicians and patients (Directive to Take Action); and be it further

RESOLVED, That our AMA support any effort to allow the physician to bill the insurance company directly for prior authorization time, and that the cost not be a pass-through charge to the patient (New HOD Policy); and be it further

RESOLVED, That our AMA work, both by administrative and/or legislative means, to address the problem of excessive burden from prior authorizations and meaningful use regulations by regulatory and/or legislative means (Directive to Take Action); and be it further

RESOLVED, That our AMA work with Medicare Advantage plans to follow Medicare guidelines if the plan chooses to follow their own guidelines. The plan must be transparent on the criteria for approval or denial. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 09/26/17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 805
(I-17)

Introduced by: Montana

Subject: A Dual System for Universal Health Care in the United States

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, The delivery and finance of healthcare in the United States is at imminent risk of collapse; and

Whereas, The Affordable Care Act has not stabilized the delivery and finance of healthcare in the United States; and

Whereas, The steadily rising US healthcare expenditures threaten the financial viability of the people, corporations, municipal, state and federal governments of the United States; and

Whereas, The people of the United States have deep philosophical and political divisions regarding the proper reform of our healthcare system; and

Whereas, The achievement of a fully socialized or fully privatized healthcare system is politically impossible and ill-advised given our current status quo; and

Whereas, People of the United States have the freedom to choose the terms under which we receive our healthcare; and

Whereas, We believe it is our right as physicians to choose the terms under which we provide our professional services; and

Whereas, It is our duty as physicians to advocate for quality healthcare services on behalf of all patients who need our services; and

Whereas, The ongoing ideological battle is leading to the failure of both private and government healthcare in the United States; and

Whereas, The ongoing dysfunction in our system is having a severely corrosive effect on the profession of medicine and the patient doctor relationship; and

Whereas, The public and private healthcare systems successfully co-exist in other developed nations; and

Whereas, The public and private services successfully co-exist in other parts of the economy such as transportation, utilities, housing, legal services and education; and

Whereas, It should be politically possible at this moment to craft legislation which forward the agenda and objectives of those who favor a public system and those who favor a private system; therefore be it

RESOLVED, That our American Medical Association vigorously advocate for compromise health care reform legislation which restructures all existing government health care programs into a single universal government system which provides health care to all United States citizens and legal residents at a level which is sustainable and affordable (Directive to Take Action); and be it further

RESOLVED, That our AMA simultaneously, with equal vigor, advocate for a far reaching deregulation of privately purchased health care, while maintaining the emphasis on improving quality and safety (Directive to Take Action); and be it further

RESOLVED, That our AMA resist all legislation which attempts to coerce or infringe upon the freedom of the people of the United States to choose the terms of their health care (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for both public and private health care reforms as an inseparable package. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 09/27/17

RELEVANT AMA POLICY

Health System Reform Legislation H-165.838

Individual Health Insurance H-165.920

Preservation of Physician-Patient Relationships and Promotion of Continuity of Patient Care H-160.901

Access to Affordable Health Care Insurance through Deregulation of State Mandated Benefits H-180.978

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 806
(I-17)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Subject: Mandate Transparency by Pharmacy Benefit Managers

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, There have been numerous documented cases of pharmacy benefit managers (PBM) and local pharmacies charging much higher prices for prescription generic medications if insured, than if these medications were being paid by cash without insurance, thereby raising patient co-pays needlessly;[1,2,3] and

Whereas, Pharmacy benefit manager's contracts are cloaked in secrecy, not allowing patients to see the true cost of medications;[3,4,5] and

Whereas, Such PBM practices drive up the cost prescription medications and insurance cost enriching PBM's and pharmacies;[2,3,5] and

Whereas, There is now evidence of widespread price gouging by PBM;[4,5] and

Whereas, PBM's are thinly regulated allowing these abuses to occur;[5,6] therefore be it

RESOLVED, That our American Medical Association ask Congress and other appropriate entities to require that there be transparency of drug pricing by pharmacy benefit managers (PBM) to help prevent PBM price manipulation of patient prescription costs (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for policy that retail pharmacies and health plans be required to disclose to patients the lowest possible cost of any prescription medication--specifically, any price differential between the price of a drug when using an insurance benefit vs the price of the drug without using that benefit. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 09/28/17

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[1] "Why Are Drug Prices So High? We're Curious, Too", NYT, by Katie Thomas and Charles Ornstein, Set 17, 2017
[2] "Generic prices are falling, but are consumers benefiting? NYT, by Charles Ornstein and Katie Thomas, Aug 8, 2017
[3] "The 'clawback': Another hidden scam driving up your prescription price"LA times, by Michael Hiltzik, august 9, 2017
[4] "New White Paper Details Bureaucracy, Deadly Delays, and Apathy by Pharmacy Benefit Managers" By Nicolas Ferreyros, Community Oncology Alliance, September 19, 2017
[5] State Initiatives to Control Medication Costs--Can Transparency Legislation Help? Ameet Sarpatwari, J.D., Ph.D., Jerry Avorn, M.D., and Aaron S. Kesselheim, M.D., J.D., M.P.H. NEJM June 16, 2016
[6] Undermining Value-Based Purchasing — Lessons from the Pharmaceutical Industry Leemore S. Dafny, Ph.D., Christopher J. Ody, Ph.D., and Matthew A. Schmitt, Ph.D. NEJM, Nov 24,2016

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 807
(I-17)

Introduced by:	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Subject:	Structural Barriers to Achieving Better Health Care Efficiency and Outcomes: ACOs and Physician Employment by Hospitals
Referred to:	Reference Committee J (Peter C. Amadio, MD, Chair)

Whereas, Accountable Care Organizations (ACOs) have been promoted for their putative ability to “bend the cost curve” and reduce total medical expenditures; and

Whereas, Physician employment by hospitals has been increasing; and

Whereas, Increasing physician employment has been reported to be a contributor to physician burnout; and

Whereas, "Site of service" payment differentials are causing an unfair advantage favoring hospital employment over independent practice; and

Whereas, Despite early hopes that physicians would lead ACOs, most ACOs are in fact controlled by hospitals and hospital systems; and

Whereas, Hospital-controlled ACOs have sometimes created restrictive referral policies that serve to promote hospital services rather than to seek the lower cost, higher quality, or more accessible location for given service; therefore be it

RESOLVED, That our American Medical Association study and report back on health system-led Accountable Care Organization related barriers to utilizing the site of service determined by the physician to be in the best interest of the patient. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 09/28/17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 808
(I-17)

Introduced by:	American Academy of Dermatology, American Society for Dermatologic Surgery Association, American College of Mohs Surgery, American Society of Dermatopathology, Society for Investigative Dermatology, American College of Allergy, Asthma and Immunology, Florida
Subject:	Opposition to Reduced Payment for the 25 Modifier
Referred to:	Reference Committee J (Peter C. Amadio, MD, Chair)

Whereas, Several insurers--including Independence Blue Cross, Blue Cross Blue Shield Rhode Island, Harvard Pilgrim Health Care, and Tufts Health Plan--have implemented policies that inappropriately reduce reimbursement for modifier 25; and

Whereas, Anthem announced it will implement the same policy in Kentucky, Ohio and Wisconsin in January of 2018; and

Whereas, When an Evaluation & Management (E/M) code with modifier 25 and a procedure code are billed by the same provider for the same date of service, these plans will only compensate the E/M service at 50 percent of the otherwise allowed amount; and

Whereas, The intent of modifier 25, according to Current Procedural Terminology (CPT) guidelines, is to describe a significant, separately identifiable, and medically necessary E/M service performed on the same day as a procedure, outside of the global fee concept; and

Whereas, Providing medically necessary, distinct services on the same date allows physicians to provide effective and efficient, high quality care, in many cases saving patients a return visit; and

Whereas, The AMA Relative Value Scale (RVS) Update Committee (RUC) already reduces the reimbursement for surgical codes that are typically reported with an E/M to account for any overlapping pre-and post-operative work; and

Whereas, By having an insurer impose a reduction on the E/M service, the insurer is in effect reimbursing both codes at a reduced rate; and

Whereas, If there is not a strong response from the House of Medicine the policy will likely spread to other insurers; and

Whereas, Increased uptake in this policy would lead to reimbursement below the cost of physician expense, patients incurring higher out of pocket costs due to follow up visit, and longer waits to see a specialist; therefore be it

RESOLVED, That our American Medical Association amend Policy D-70.971 by addition and deletion to read as follows:

Uses and Abuses of CPT Modifier -25 D-70.971
(1) Our AMA Private Sector Advocacy Group will continue to collect information on the use and acceptance of CPT modifiers, particularly modifier -25, and that it continue to advocate for the acceptance of modifiers and the appropriate ~~alteration of~~ payment based on CPT modifiers.
(2) The CPT Editorial Panel in coordination with the CPT/HCPAC Advisory Committee will continue to monitor the use and acceptance of CPT Modifiers by all payers and work to improve coding methods as appropriate.
(3) Our AMA will collect information on the use and acceptance of modifier -25 among state Medicaid plans and use this information to advocate for consistent acceptance and appropriate payment ~~adjustment~~ for modifier -25 across all Medicaid plans.
(4) Our AMA will encourage physicians to pursue, in their negotiations with third party payers, contract provisions that will require such payers to adhere to CPT rules concerning modifiers.
(5) Our AMA will include in its model managed care contract, provisions that will require managed care plans to adhere to CPT rules concerning modifiers and, in the case where a procedure is appropriately modified by a modifier – 25, require that both the procedure and evaluation and management are paid at 100% of the non-reduced, allowable payment rate.
(6) Our AMA will continue to educate physicians on the appropriate use of CPT rules concerning modifiers.
(7) Our AMA will actively work with third party payers to encourage their disclosure to physician providers any exceptions by those payers to CPT guidelines, rules and conventions.
(8) Our AMA will include in CPT educational publications (i.e. CPT Assistant) examples of commonly encountered situations where the -25 modifier would and would not apply.
(Modify Current HOD Policy)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 09/29/17

RELEVANT AMA POLICY

Uses and Abuses of CPT Modifier -25 D-70.971
(1) Our AMA Private Sector Advocacy Group will continue to collect information on the use and acceptance of CPT modifiers, particularly modifier -25, and that it continue to advocate for the acceptance of modifiers and the appropriate alteration of payment based on CPT modifiers.
(2) The CPT Editorial Panel in coordination with the CPT/HCPAC Advisory Committee will continue to monitor the use and acceptance of CPT Modifiers by all payers and work to improve coding methods as appropriate.
(3) Our AMA will collect information on the use and acceptance of modifier -25 among state Medicaid plans and use this information to advocate for consistent acceptance and appropriate payment adjustment for modifier -25 across all Medicaid plans.
(4) Our AMA will encourage physicians to pursue, in their negotiations with third party payers, contract provisions that will require such payers to adhere to CPT rules concerning modifiers.
(5) Our AMA will include in its model managed care contract, provisions that will require managed care plans to adhere to CPT rules concerning modifiers.
(6) Our AMA will continue to educate physicians on the appropriate use of CPT rules concerning modifiers.
(7) Our AMA will actively work with third party payers to encourage their disclosure to physician providers any exceptions by those payers to CPT guidelines, rules and conventions.
(8) Our AMA will include in CPT educational publications (i.e. CPT Assistant) examples of commonly encountered situations where the -25 modifier would and would not apply.
BOT Rep. 10, I-03 Reaffirmation A-10

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 809
(I-17)

Introduced by: American Academy of Dermatology, American Society for Dermatologic Surgery Association, American College of Mohs Surgery, American Society of Dermatopathology, Society for Investigative Dermatology, Florida

Subject: Expansion of Network Adequacy Policy

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, The Centers for Medicare & Medicaid Services piloted a network adequacy test in 2016 and found several plans with outdated directories; and

Whereas, Exchange plans are required to provide publically available directories and update them on a monthly basis; and

Whereas, Plans continually update networks, but often mistakenly terminate physicians; and

Whereas, As a result of the false termination patients receive notice that the physician chooses to no longer remain in the patient's network; and

Whereas, In cases where a patient has been informed about the pending termination status of a physician they have seen in the last year that is overturned the patient should receive a corrected notice from the insurer informing them the physician remains available in their selected plan; therefore be it

RESOLVED, That our American Medical Association amend Policy H-285.908 by addition to read as follows:

Network Adequacy H-285.908
12. Our AMA supports requiring that health insurers that terminate in-network providers:
a) Notify providers of pending termination at least 30 days prior to removal from network.
b) Give to providers, at least 14 days prior to distribution, a copy of the health insurer's letter notifying patients of the provider's change in network status. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/29/17

RELEVANT AMA POLICY

Network Adequacy H-285.908

1. Our AMA supports state regulators as the primary enforcer of network adequacy requirements.
2. Our AMA supports requiring that provider terminations without cause be done prior to the enrollment period, thereby allowing enrollees to have continued access throughout the coverage year to the network they reasonably relied upon when purchasing the product. Physicians may be added to the network at any time.
3. Our AMA supports requiring health insurers to submit and make publicly available, at least quarterly, reports to state regulators that provide data on several measures of network adequacy, including the number and type of providers that have joined or left the network; the number and type of specialists and subspecialists that have left or joined the network; the number and types of providers who have filed an in network claim within the calendar year; total number of claims by provider type made on an out-of-network basis; data that indicate the provision of Essential Health Benefits; and consumer complaints received.
4. Our AMA supports requiring health insurers to indemnify patients for any covered medical expenses provided by out-of-network providers incurred over the co-payments and deductibles that would apply to in-network providers, in the case that a provider network is deemed inadequate by the health plan or appropriate regulatory authorities.
5. Our AMA advocates for regulation and legislation to require that out-of-network expenses count toward a participant's annual deductibles and out-of-pocket maximums when a patient is enrolled in a plan with out-of-network benefits, or forced to go out-of-network due to network inadequacies.
6. Our AMA supports fair and equitable compensation to out-of-network providers in the event that a provider network is deemed inadequate by the health plan or appropriate regulatory authorities.
7. Our AMA supports health insurers paying out-of-network physicians fairly and equitably for emergency and out-of-network bills in a hospital. AMA policy is that any legislation which addresses this issue should assure that insurer payment for such care be based upon a number of factors, including the physicians' usual charge, the usual and customary charge for such service, the circumstances of the care and the expertise of the particular physician.
8. Our AMA provides assistance upon request to state medical associations in support of state legislative and regulatory efforts, and disseminate relevant model state legislation, to ensure physicians and patients have access to adequate and fair appeals processes in the event that they are harmed by inadequate networks.
9. Our AMA supports the development of a mechanism by which health insurance enrollees are able to file formal complaints about network adequacy with appropriate regulatory authorities.
10. Our AMA advocates for legislation that prohibits health insurers from falsely advertising that enrollees in their plans have access to physicians of their choosing if the health insurer's network is limited.
11. Our AMA advocates that health plans should be required to document to regulators that they have met requisite standards of network adequacy including hospital-based physician specialties (i.e. radiology, pathology, emergency medicine, anesthesiologists and hospitalists) at in-network facilities, and ensure in-network adequacy is both timely and geographically accessible.

Citation: CMS Rep. 4, I-14; Reaffirmation I-15; Reaffirmed in lieu of Res. 808, I-15; Modified: Sub. Res. 811, I-15; Reaffirmed: CMS Rep. 03, A-17; Reaffirmed: Res. 108, A-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 810
(I-17)

Introduced by: American College of Rheumatology, American Academy of Dermatology, American Academy of Neurology, American Association of Clinical Endocrinologists, American Association of Clinical Urologists, American College of Gastroenterology, American Society of Clinical Oncology, Infectious Diseases Society of America

Subject: Pharmacy Benefit Managers and Prescription Drug Affordability

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, Pharmacy benefit managers (PBMs) play a key part in the US prescription drug industry and have significant influence over drug costs and patient access to effective and affordable treatment; and

Whereas, According to a recent poll conducted by the Kaiser Family Foundation, 77% of Americans believe the cost of prescription drugs is unreasonable; and

Whereas, The AMA's Truth in Rx advocacy campaign is designed to bring attention to rising drug costs and help develop solutions to make prescription drugs more affordable; and

Whereas, Manufacturers pay retroactive rebates to PBMs in exchange for favorable placement on their formularies, which creates perverse financial incentives that motivate PBMs to develop their formularies based on the size of the rebate they can obtain, influence list prices (higher the list price, higher the potential rebate amount), and cause many patients to be denied coverage for their prescribed medication due to an unnecessary formulary restriction; and

Whereas, Patient cost-sharing obligations such as deductibles and coinsurance are calculated based off of the list price and not the actual net price that takes into manufacturer rebates, which greatly increases out-of-pocket costs for the many patients; and

Whereas, Physicians are now held to account for spending per patient episode, and risk being removed from networks based on that spend; and

Whereas, Step therapy, prior authorization, and other utilization management techniques used by insurers and largely stem from the formulary restrictions caused by the rebate system and not only impede patient access to effective and appropriate treatment, but also place a cumbersome and even crippling administrative burden on physicians; and

Whereas, PBM practices have greatly impacted the ability of providers to appropriately treat and effectively care for their patients; therefore be it

RESOLVED, That our American Medical Association expand the Truth in Rx advocacy campaign to include and explicitly address through educational outreach the effects of pharmacy benefit manager (PBM) practices on drug prices and access to affordable treatment (Directive to Take Action); and be it further

RESOLVED, That our AMA engage in efforts to educate federal lawmakers about the role of PBM practices in drug pricing and urge Congressional action to increase transparency of PBM practices (Directive to Take Action); and be it further

RESOLVED, That our AMA work at the federal and state level to increase transparency for PBMs by: eliminating increases in patient cost-sharing obligations for prescription drugs if such drugs are chosen for profit to the PBM; restricting PBM use of non-medical switching and other utilization management techniques related to PBM formulary development that disrupt the patient treatment plan; and further regulating PBM practices in order to ensure patients have access to effective and affordable medication therapies (Directive to Take Action); and be it further

RESOLVED, That our AMA develop model guidelines for effective and meaningful transparency in the rebate system, to include PBM and health plan disclosure to physicians of the contracted cost of medications including discounts and rebates from manufacturers paid back to health plans and PBMs, and urge PBMs to take active steps to implement those guidelines. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 09/29/17

RELEVANT AMA POLICY

Pharmaceutical Cost H-110.987
1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10.Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.
Citation: CMS Rep. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Appended: Res. 201, A-17; Reaffirmed in lieu of: Res. 207, A-17; Modified: Speakers Rep. 01, A-17;

See also: Pharmaceutical Benefits Management Companies H-125.986, Inappropriate Actions by Pharmacies and Pharmacy Benefit Managers D-120.988; Interference in the Practice of Medicine D-125.997; Private Health Insurance Formulary Transparency H-125.979; Expanded Use of the AMA's Principles of a Sound Drug Formulary H-125.985; Health Plan Coverage of Prescription Drugs D-125.995; Health Plan Coverage of Prescription Drugs D-185.995; Access to Self-Administered Medications H-120.931

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 811
(I-17)

Introduced by: Michigan

Subject: Update OBRA Nursing Facility Preadmission Screening Requirements

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, Preadmission Screening and Resident Review (PASRR) is a federal requirement, which was originally enacted as part of the Nursing Home Reform Act under the Omnibus Reconciliation Act of 1987 (OBRA), designed to protect patients with serious mental illness or intellectual disabilities from lack of access to proper mental health care services and from possible inappropriate admission and retention in nursing facilities; and

Whereas, Although states are required to have a PASRR program whereby applicants to Medicaid-certified nursing facilities receive a comprehensive mental health assessment if they are identified as having a serious mental illness or intellectual disability, there is much variation in how PASRR is implemented across states; and

Whereas, This screening process is comprised of two steps--a Level I screening to identify individuals with a PASRR disability and a Level II screening if the Level I screening indicates an individual may have a serious mental illness or intellectual disability; and

Whereas, The results of the Level II evaluation provide recommendations pertaining to need, appropriate care setting, and necessary specialized services; and

Whereas, The completion time for Level II screening can take up to four to five business days; and

Whereas, Coverage under Medicare Part A funding for a skilled nursing facility (SNF) stay has necessitated a three-day hospital stay in the past, often leading to unnecessarily prolonged lengths of stay for acute inpatient hospitalizations with resultant increases in the total cost of care for many patients; and

Whereas, The development of several payment models such as the Bundled Payment Care Improvement Initiative, Medicare Shared Savings Program Accountable Care Organizations, and other Alternative Payment Models under the Medicare Access and CHIP Reauthorization Act of 2015 has led to a potential waiver of the three-day stay to allow more timely transfer of patients requiring SNF services (sub-acute rehabilitation or long-term care) with a possible reduction in the total cost of care for many patients; and

Whereas, The need for the completion of the PASRR screening prior to admission to a SNF essentially invalidates the potential for more immediate transfers to SNFs from emergency rooms, physicians' offices, or even other levels of care within the continuum of a nursing facility; therefore be it

RESOLVED, That our American Medical Association work with the US Department of Health and Human Services and Congress to amend applicable statutes and regulations to revise the Preadmission Screening and Resident Review requirement for nursing facility placement to provide more consistent enactment among states and to allow more reasonable and cost-effective approaches to this mandatory screening process. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 09/29/17

RELEVANT AMA POLICY

Direct Admission of Medicare Patients to Skilled Nursing Facilities H-280.977
Our AMA supports regulatory change and any necessary legislation which would delete the 3-day prior hospitalization requirement for provision of skilled nursing facility benefits under Medicare, so as to allow coverage for direct admission of Medicare patients to a skilled nursing facility whether or not they have been discharged from an acute care hospital within the last 30 days.
Citation: (Res. 33, A-91; Res. 48, I-81; Reaffirmed: CLRPD Rep. F, I-91; CMS Rep. 11, I-95; Reaffirmation A-97; Reaffirmation I-00; Reaffirmed: Res. 730, A-06; Reaffirmed: Res. 234, A-09; Reaffirmed: BOT Rep. 32, A-09; Reaffirmation A-11; Reaffirmation A-15)

Three Day Stay Rule H-280.947
1. Our American Medical Association will continue to advocate that Congress eliminate the three-day hospital inpatient requirement for Medicare coverage of post-hospital skilled nursing facility services, and educate Congress on the impact of this requirement on patients.
2. Our AMA will continue to advocate, as long as the three-day stay requirement remains in effect, that patient time spent in the hospital, observation care or in the emergency department count toward the three-day hospital inpatient requirement for Medicare coverage of post-hospital skilled nursing facility services.
3. Our AMA will actively work with the Centers for Medicare and Medicaid Services (CMS) to eliminate any regulations requiring inpatient hospitalization as a prerequisite before a Medicare beneficiary is eligible for skilled (SNF) or long-term care (LTC) placement.
Citation: (Sub. Res. 103, A-15; Res. 110, A-15)

Inclusion of Observation Status in Mandatory Three Day Inpatient Stay D-280.989
1. Our AMA will continue to monitor problems with patient readmissions to hospitals and skilled nursing facilities and recoding of inpatient admissions as observation care and advocate for appropriate regulatory and legislative action to address these problems.
2. Our AMA will continue to advocate that the Centers for Medicare & Medicaid Services explore payment solutions to reduce the inappropriate use of hospital observation status.
Citation: (BOT Rep. 32, A-09; Appended: CMS Rep. 4, A-14)

Observation Status and Medicare Part A Qualification D-280.988
Our AMA will advocate for Medicare Part A coverage for a patient's direct admission to a skilled facility if directed by their physician and if the patient's condition meets skilled nursing criteria.
Citation: (Res. 117, A-13; Reaffirmed: CMS Rep. 4, A-14; Reaffirmation A-15)

Three Day Prior Hospital Stay Requirement H-330.948
Our AMA will recommend that the Secretary of the U.S. Department of Health and Human Services, in consultation with health care professionals and skilled care providers, define a subset of patients (or DRGs) for whom the elimination of the three day prior hospital stay requirement for eligibility of the Medicare Skilled Nursing Facility benefit would avert hospitalization and generate overall cost savings.
Citation: (Res. 805, I-93; Reaffirmation A-97; Reaffirmation I-00; Reaffirmation A-04; Reaffirmed: Res. 234, A-09; Reaffirmation A-11)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 812
(I-17)

Introduced by: Michigan

Subject: Medicare Coverage of Services Provided by Proctored Medical Students

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, Current trends in medical education in the US often lead to medical students providing medical services under the practiced eyes of proctoring medical professionals (both teaching physicians and other health care providers such as medical assistants and respiratory therapists); and

Whereas, Services provided by intern or resident physicians are billable under Centers for Medicare and Medicaid Services (CMS) through the Medicare Physician Fee Schedule if a teaching physician is physically present during the critical or key portions of the service; and

Whereas, Services provided by medical students (such as obtaining a Pap smear or setting up a nebulizer treatment) are not currently billable under CMS even if proctoring medical professionals are directly assisting or overseeing the service as part of medical education; and

Whereas, The inability to bill for these services may result in unnecessary duplication of services for patients, including the potential risk of repetitive minor procedures; and

Whereas, The inability to bill for these services may also result in restrictions in medical student education access since the educational facility may not be able to sustain the educational process without the procedural revenue; therefore be it

RESOLVED, That our American Medical Association amend Policy, H-390.999, “Payments to Physicians in Teaching Setting by Medicare Fiscal Intermediaries,” by addition as follows:

> When a physician assumes responsibility for the services rendered to a patient by a medical student, a resident, or an intern, the physician may ethically bill the patient for services which were performed under the physician's personal observation, direction, and supervision (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA work with the Centers for Medicare and Medicaid Services to require coverage of medical services performed by medical students while under the physician's personal observation, direction, and supervision. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 09/29/17

RELEVANT AMA POLICY

Payments to Physicians in Teaching Setting by Medicare Fiscal Intermediaries H-390.999
When a physician assumes responsibility for the services rendered to a patient by a resident or an intern, the physician may ethically bill the patient for services which were performed under the physician's personal observation, direction, and supervision.
Citation: (CMS Rep. H, A-77; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CMS Rep. 6, A-10)

Clinical Proctoring H-375.974
AMA policy states that clinical proctoring is an important tool for education and the evaluation of clinical competence of new physicians seeking privileges or existing medical staff members requesting new privileges. Therefore, the AMA:
(1) encourages hospital medical staffs to develop proctoring programs, with appropriate medical staff bylaws provisions, to evaluate the clinical competency of new physicians seeking privileges and existing medical staff members requesting new privileges; and
(2) encourages hospital medical staffs to consider including the following provisions in their medical staff bylaws for use in their proctoring program:
(a) Except as otherwise determined by the medical executive committee, all initial appointees to the medical staff and all members granted new clinical privileges shall be subject to a period of proctoring.
(b) Each appointee or recipient of new clinical privileges shall be assigned to a department where performance of an appropriate number of cases as established by the medical executive committee, or the department as designee of the medical executive committee, shall be observed by the chair of the department, or the chair's designee, during the period of proctoring specified in the department's rules and regulations, to determine the suitability to continue to exercise the clinical privileges granted in that department. The exercise of clinical privileges in any other department shall also be subject to direct observation by that department's chair or the chair's designee.
(c) The members shall remain subject to such proctoring until the medical executive committee has been furnished with: a report signed by the chair of the department(s) to which the member is assigned as well as other department(s) in which the appointee may exercise clinical privileges, describing the types and numbers of cases observed and the evaluation of the applicant's performance, a statement that the applicant appears to meet all of the qualifications for unsupervised practice in that department, has discharged all of the responsibilities of staff membership, and has not exceeded or abused the prerogative of the category to which the appointment was made, and that the member has satisfactorily demonstrated the ability to exercise the clinical privileges initially granted in those departments.
Citation: (BOT Rep. 30-A-94; Amended: CMS Rep. 3, A-99; Reaffirmed: CLRPD Rep. 1, A-09)

Supervision and Proctoring by Facility Medical Staff H-375.967
Our AMA advocates that the conduct of medical staff supervision be included in medical staff bylaws and be guided by the following principles:
(1) Physicians serving as medical staff supervisors should be indemnified at the facility's expense from malpractice claims and other litigation arising out of the supervision function.
(2) Physicians being supervised should be indemnified at the facility's expense for any damages that might occur as a result of implementing interventions recommended by medical staff supervisors.
(3) AMA principles of peer review as found in Policies H-320.968 [2,d], H-285.998 [5], and H-320.982 [2c,d] should be adhered to in the conduct of medical staff supervision.
(4) The medical staff member serving as supervisor should be determined through a formal process by the department chair or medical staff executive committee.
(5) The scope of the medical staff supervision should be limited to the provision of services that have been restricted, are clearly questionable, or are under question, as determined by the department chair or medical staff executive committee.
(6) The duration of the medical staff supervision should be limited to the amount of time necessary to adequately assess the degree of clinical competence in the area of skill being assessed.
(7) Medical staff supervision should include a sufficient volume of procedures or admissions for meaningful assessment.
(8) Medical staff supervisors should provide periodic performance reports on each patient to the appropriate designated medical staff committee. The reports should be transcribed or transcripted by the medical staff office to assure confidentiality. The confidentiality of medical staff supervision reports must be strictly maintained.
(9) Physicians whose performance is supervised should have access to the performance reports submitted by medical staff supervisors and should be given the opportunity to comment on the contents of the reports.
Citation: (CMS Rep. 3, A-99; Reaffirmed: CLRPD Rep. 1, A-09)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 813
(I-17)

Introduced by: Michigan

Subject: Sustain Patient-Centered Medical Home Practices

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, The Patient-Centered Medical Home (PCMH) practice model has been implemented throughout the health care delivery system for several years; and

Whereas, Third-party payers are benefiting from the hard work of physicians; and

Whereas, The ongoing costs to physicians to sustain PCMH are significant; therefore be it

RESOLVED, That our American Medical Association amend Policy, H-160.918, "The Patient-Centered Medical Home," by addition as follows:

Our AMA:
1. will urge the Centers for Medicare and Medicaid Services (CMS) to work with our AMA and national medical specialty societies to design incentives to enhance care coordination among providers who provide medical care for patients outside the medical home;
2. will urge CMS to assist physician practices seeking to qualify for <u>and sustain</u> medical home status with financial and other resources;
3. will advocate that Medicare incentive payments associated with the medical home model be paid for through system-wide savings--such as reductions in hospital admissions and readmissions (Part A), more effective use of pharmacologic therapies (Part D), and elimination of government subsidies for Medicare Advantage plans (Part C)--and not be subject to a budget neutrality offset in the Medicare physician payment schedule; and
4. will advocate that all health plans and CMS use a single standard to determine whether a physician practice qualifies to be a patient-centered medical home. (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA work with and encourage the Centers for Medicare and Medicaid Services to subsidize the cost of sustaining Patient-Centered Medical Home designated practices for practicing physicians. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 09/29/17

RELEVANT AMA POLICY

The Patient-Centered Medical Home H-160.918
Our AMA:
1. will urge the Centers for Medicare and Medicaid Services (CMS) to work with our AMA and national medical specialty societies to design incentives to enhance care coordination among providers who provide medical care for patients outside the medical home;
2. will urge CMS to assist physician practices seeking to qualify for medical home status with financial and other resources;
3. will advocate that Medicare incentive payments associated with the medical home model be paid for through system-wide savings--such as reductions in hospital admissions and readmissions (Part A), more effective use of pharmacologic therapies (Part D), and elimination of government subsidies for Medicare Advantage plans (Part C)--and not be subject to a budget neutrality offset in the Medicare physician payment schedule; and
4. will advocate that all health plans and CMS use a single standard to determine whether a physician practice qualifies to be a patient-centered medical home.
Citation: (CMS Rep. 8, A-09)

See also: Principles of the Patient-Centered Medical Home H-160.919

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 814
(I-17)

Introduced by: American Academy of Physical Medicine and Rehabilitation

Subject: Appropriate Reimbursement for Evaluation and Management Services for Patients with Severe Mobility-Related Impairments

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, People with severe mobility impairments often face significant challenges to access of medical care due to problems with cognition, communication, mobility, community access, insurance, and providers' lack of familiarity with the needs and preferences of people with disabilities; and

Whereas, Care provided for patients with severely impaired mobility requires greater investment of time, staff, and office equipment such as adjustable height chairs or tables, patient lift teams or electric lifts, and adjustable leg supports; and

Whereas, Current reimbursement structures for evaluation and management services (E/M) do not account for the increased time and investment needed to provide comprehensive patient centered care for patients with severely impaired mobility, and thus have the potential to decrease access to appropriate and timely medical care for these patients; therefore be it

RESOLVED, That our American Medical Association support additional reimbursement for evaluation and management services for patients who require additional time and specialized equipment during medical visits due to severe mobility-related impairments (New HOD Policy); and be it further

RESOLVED, That our AMA support that no additional cost-sharing for the additional reimbursement will be passed on to patients with mobility disabilities, consistent with Federal Law (New HOD Policy); and be if further

RESOLVED, That our AMA support that primary and specialty medical providers be educated regarding the care of patients with severely impaired mobility to improve access to care. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 10/05/17

References:

National Healthcare Disparities Report, 2013. Content last reviewed May 2014. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/research/findings/nhqrdr/nhdr13/index.html

RELEVANT AMA POLICY

Federal Legislation on Access to Community-Based Services for People with Disabilities H-290.970 - Our AMA strongly supports reform of the Medicaid program established under title XIX of the Social Security Act (42 U.S.C. 1396) to provide services in the most appropriate settings based upon the individual's needs, and to provide equal access to community-based attendant services and supports. *Citation: Res. 917, I-07; Reaffirmed: BOT Rep. 22, A-17*

Medical Care of Persons with Developmental Disabilities H-90.968
1. Our AMA encourages: (a) clinicians to learn and appreciate variable presentations of complex functioning profiles in all persons with developmental disabilities; (b) medical schools and graduate medical education programs to acknowledge the benefits of education on how aspects in the social model of disability (e.g. ableism) can impact the physical and mental health of persons with Developmental Disabilities; (c) medical schools and graduate medical education programs to acknowledge the benefits of teaching about the nuances of uneven skill sets, often found in the functioning profiles of persons with developmental disabilities, to improve quality in clinical care; (d) the education of physicians on how to provide and/or advocate for quality, developmentally appropriate medical, social and living supports for patients with developmental disabilities so as to improve health outcomes; (e) medical schools and residency programs to encourage faculty and trainees to appreciate the opportunities for exploring diagnostic and therapeutic challenges while also accruing significant personal rewards when delivering care with professionalism to persons with profound developmental disabilities and multiple co-morbid medical conditions in any setting; (f) medical schools and graduate medical education programs to establish and encourage enrollment in elective rotations for medical students and residents at health care facilities specializing in care for the developmentally disabled; and (g) cooperation among physicians, health & human services professionals, and a wide variety of adults with developmental disabilities to implement priorities and quality improvements for the care of persons with developmental disabilities.
2. Our AMA seeks: (a) legislation to increase the funds available for training physicians in the care of individuals with intellectual disabilities/developmentally disabled individuals, and to increase the reimbursement for the health care of these individuals; and (b) insurance industry and government reimbursement that reflects the true cost of health care of individuals with intellectual disabilities/developmentally disabled individuals.
3. Our AMA entreats health care professionals, parents and others participating in decision-making to be guided by the following principles: (a) All people with developmental disabilities, regardless of the degree of their disability, should have access to appropriate and affordable medical and dental care throughout their lives; and (b) An individual's medical condition and welfare must be the basis of any medical decision. Our AMA advocates for the highest quality medical care for persons with profound developmental disabilities; encourages support for health care facilities whose primary mission is to meet the health care needs of persons with profound developmental disabilities; and informs physicians that when they are presented with an opportunity to care for patients with profound developmental disabilities, that there are resources available to them.
4. Our AMA will continue to work with medical schools and their accrediting/licensing bodies to encourage disability related competencies/objectives in medical school curricula so that medical professionals are able to effectively communicate with patients and colleagues with disabilities, and are able to provide the most clinically competent and compassionate care for patients with disabilities.
5. Our AMA recognizes the importance of managing the health of children and adults with developmental disabilities as a part of overall patient care for the entire community.
6. Our AMA supports efforts to educate physicians on health management of children and adults with developmental disabilities, as well as the consequences of poor health management on mental and physical health for people with developmental disabilities.
7. Our AMA encourages the Liaison Committee on Medical Education, Commission on Osteopathic College Accreditation, and allopathic and osteopathic medical schools to develop and implement curriculum on the care and treatment of people with developmental disabilities.
8. Our AMA encourages the Accreditation Council for Graduate Medical Education and graduate medical education programs to develop and implement curriculum on providing appropriate and comprehensive health care to people with developmental disabilities.
9. Our AMA encourages the Accreditation Council for Continuing Medical Education, specialty boards, and other continuing medical education providers to develop and implement continuing education programs that focus on the care and treatment of people with developmental disabilities. *Citation: CCB/CLRPD Rep. 3, A-14; Appended: Res. 306, A-14; Appended: Res. 315, A-17*

Equal Access for Physically Challenged Physicians H-90.987 - Our AMA supports equal access to all hospital facilities for physically challenged physicians as part of the Americans with Disabilities Act. *Citation: (Res. 816, I-91; Reaffirmed: Sunset Report, I-01; Modified: CSAPH Rep. 1, A-11*

See also: Community Mobility Devices H-90.978; Access to Public Buildings for Handicapped Persons H-90.999; Enhancing Accommodations for People with Disabilities H-90.971

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 815
(I-17)

Introduced by: American Academy of Pediatrics

Subject: Pediatric Representation for E/M Documentation Guideline Revision

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, The Centers for Medicare and Medicaid Services (CMS) expressed desire to revise current Evaluation and Management (E/M) documentation guidelines; and

Whereas, AMA also publishes E/M documentation guidelines in its annual CPT book; and

Whereas, The medical provider community benefits from the regulatory clarity achieved when both CMS and CPT documentation guidelines are aligned and consistent (as well as when other payer documentation requirements, such as those of Medicaid programs, are aligned) with CMS/Medicare and CPT; and

Whereas, Pediatric caregivers confront unique history, physical exam, and medical decision making challenges in documenting their patients' care both from the perspective of progressively advancing age as well as evolving developmental stage; and

Whereas, The American Academy of Pediatrics is a fully committed participant in the CPT process and has extensive experience in representing the clinical and coding needs of the pediatric community; therefore be it

RESOLVED, That, in the process of collaborating with the Centers for Medicare and Medicaid Services for the future revision of Evaluation and Management Documentation Guidelines, our American Medical Association rely on the American Academy of Pediatrics in addressing the needs of pediatricians and their patients. (New HOD Policy)

Fiscal Note: None

Received: 10/11/17

References:
Proposed Rule, Department of Health and Human Services, Centers for Medicare and Medicaid Services, 42 CFR Parts 405, 410, 414, 424, 425, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (Page 374 of PDF).

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 816
(I-17)

Introduced by: American College of Preventive Medicine

Subject: Social Determinants of Health in Payment Models

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, Healthy People 2020 defines "social determinants of health" as "conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks"[1]; and

Whereas, The estimated number of deaths attributable to social factors in the United States is comparable to the number attributed to pathophysiological and behavioral causes[2]; and

Whereas, There is strong evidence that increased investment in selected social services and models of partnership between healthcare and social services (including housing support, nutrition assistance, case management, and integrated healthcare and housing services) can confer substantial health benefits and reduce healthcare costs for targeted populations[3]; and

Whereas, Programs such as the Medicaid-funded Community Support Program for People Experiencing Chronic Homelessness (CSPECH), started in 2006 by the Massachusetts Behavioral Health Partnership and the Massachusetts Housing and Shelter Alliance, are associated with up to an $11,914 reduction in annual per-person healthcare costs and an annual per-person net savings of up to $7,013[4]; and

Whereas, A National Quality Forum panel of experts suggests that not adjusting for patients' sociodemographic factors might actually harm patients, exacerbate disparities in care, and produce misleading performance scores for a variety of providers[5]; and

Whereas, Even though a shift has begun from paying for volume (fee-for-service) to paying for quality, known as value-based payment (VBP), there is concern that VBP designs that don't account for social risk factors could harm socially at-risk populations[6]; and

Whereas, An ad hoc committee, requested by the Department of Health and Human Services and convened by the National Academies of Sciences, Engineering, and Medicine, found that changes to the current VBP system to account for social risk factors would especially influence the lives of patients who have historically experienced barriers to accessing high-quality

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[1] US Department of Health and Human Services, Office of Disease Prevention and Health Promotion. www.healthypeople.gov.
[2] Sandro Galea, et al. "Estimated Deaths Attributable to Social Factors in the United States," American Journal of Public Health, August 2011.
[3] Yale Global Health Leadership Institute, "Leveraging Social Determinants of Health: What Works?" The Blue Cross Blue Shield of Massachusetts Foundation. June 29, 2015.
[4] Massachusetts Medicaid Policy Institute (MMPI), "Estimating Cost Reductions Associated with the Community Support Programs for People Experiencing Homelessness," The Blue Cross Blue Shield of Massachusetts Foundation. March 2017.
[5] National Quality Forum, Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors: Technical Report, August 2014.
[6] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

healthcare, and that accounting for social risk factors in quality measurement and payment in combination with complementary approaches may achieve the policy goals of reducing disparities in access, quality, and outcomes and promote health equity[6]; therefore be it

RESOLVED, That our American Medical Association support payment reform policy proposals that incentivize screening for social determinants of health, as defined by Healthy People 2020, and referral to community support systems. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 10/12/17

RELEVANT AMA POLICY

Educating Medical Students in the Social Determinants of Health and Cultural Competence H-295.874
Our AMA: (1) Supports efforts designed to integrate training in social determinants of health and cultural competence across the undergraduate medical school curriculum to assure that graduating medical students are well prepared to provide their patients safe, high quality and patient-centered care. (2) Supports faculty development, particularly clinical faculty development, by medical schools to assure that faculty provide medical students' appropriate learning experiences to assure their cultural competence and knowledge of social determinants of health. (3) Supports medical schools in their efforts to evaluate the effectiveness of their social determinants of health and cultural competence teaching of medical students, for example by the AMA serving as a convener of a consortium of interested medical schools to develop Objective Standardized Clinical Exams for use in evaluating medical students' cultural competence. (4) Will conduct ongoing data gathering, including interviews with medical students, to gain their perspective on the integration of social determinants of health and cultural competence in the undergraduate medical school curriculum. (5) Recommends studying the integration of social determinants of health and cultural competence training in graduate and continuing medical education and publicizing successful models.
Citation: CME Rep. 11, A-06; Reaffirmation A-11; Modified in lieu of Res. 908, I-14; Reaffirmed in lieu of Res. 306, A-15

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 817
(I-17)

Introduced by: New Mexico

Subject: Addressing the Site of Service Differential

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, Health care costs continue to rise faster than the rate of inflation, and are now approaching 20% of GDP, and the country cannot afford to continue diverting resources into health care from other sectors of the economy such as education and infrastructure; and

Whereas, Hospitals and hospital owned outpatient clinics are paid under the Hospital Outpatient Prospective Payment System (HOPPS), and are given an annual increase of approximately 3% based on the government's Market Basket estimate of the cost of providing health care, goods and services by hospitals; and

Whereas, Practice expense has increased by inflation, but also by increased regulatory requirements, including EHRs, data submission to attempt to measure quality, Medicare Advantage plans imposing all the prior authorization requirements of commercial plans but paying at Medicare rates; and

Whereas, Many practices now offer sophisticated outpatient services such as imaging, infusion, extensive laboratory support, etc., and must purchase the same equipment and hire the same personnel as hospitals, but are unable to charge facility fees to cover the infrastructure costs the way hospitals can, further widening the difference in infrastructure expenses between practices and hospitals; and

Whereas, Physician fees paid under the Physician Fee Schedule (PFS) did not increase under the 15 years of the Sustainable Growth Rate (SGR) law, and are only increasing a fraction of a percent under MACRA, thus creating a large and increasing Site of Service Differential between the payment to hospitals and the payment to practices not owned by hospitals, for exactly the same services; and

Whereas, The ongoing widening of the Site of Service Differential has made it increasingly difficult for independent practices to compete with hospital owned practices, resulting in the accelerated acquisition of practices by hospitals and therefore a shift from the less expensive PFS to the much more expensive HOPPS, increasing health care costs and decreasing patient and physician choice, without any proven increase in quality of care; and

Whereas, MedPAC in its June 2017 report[1] and in previous reports to Congress, expressed concerns "that consolidation among and between hospitals and physicians has increased prices without any increase in quality… [and] by creating true 'site-neutral' payments, the Medicare program could be further insulated from the cost of physician–hospital consolidation"; and

[1] http://bit.ly/MedPAC-site-neutral

Whereas, Hospitals attempt to justify the higher HOPPS payment by claiming that they provide more charity care than independent practices, but there is no good data on the amount of charity care given by hospitals or independent practices, nor any clarity regarding the methods by which uncompensated care is estimated or compared, nor consideration of the fact that under Medicare, hospital owned practices can collect a significant percentage of billed charges for uncompensated care but independent practices cannot; and

Whereas, Practice expense has not been studied since the Practice Expense Advisory Committee completed its work over a decade ago; and

Whereas, Existing AMA Policies (H-330.925 and D-330.997) address payment disparities between hospitals and ambulatory surgery centers, but there is no existing policy concerning the global Site of Service Differential issue and no policy addressing providing equivalent facility fees and equivalent uncompensated care reimbursement to independent practices and hospital owned practices; therefore be it

RESOLVED, That our American Medical Association study the Site of Service Differential with a report back no later than the 2018 Interim Meeting, including:

a) The rising gap between independent practice expenses and Medicare reimbursement, taking into account the costs of the regulatory requirements;
b) The increased cost of medical personnel and equipment, including electronic health record (EHR/EMR) purchase, software requirements, and ongoing support and maintenance;
c) The expense of maintaining hospital based facilities not common to independent practices, such as burn units and emergency departments, and determine what payment should be provided to cover those explicit costs;
d) The methodology by which hospitals report their uncompensated care, and the extent to which this is based on actual costs, not charges (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for a combined Health Care Payment System for patients who receive care that is paid for by the Centers for Medicare and Medicaid Services (CMS), that:

a) Follows the recommendation of MedPAC1 to pay "Site-Neutral" reimbursement that sufficiently covers practice expenses without regard to whether services are performed under the Hospital Outpatient Prospective Payment System (HOPPS) or the Physician Fee Schedule (PFS);
b) Pays appropriate facility fees for both hospital owned facilities and independently owned non-hospital facilities, computed using the real costs of a facility based on its fair market value; and
c) Provides independent practices with the same opportunity to receive reimbursement for uncompensated care as is provided to hospital owned practices. (New HOD Policy)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 10/12/17

RELEVANT AMA POLICY

Appropriate Payment Level Differences by Place and Type of Service H-330.925
Our AMA (1) encourages CMS to adopt policy and establish mechanisms to fairly reimburse physicians for office-based procedures; (2) encourages CMS to adopt a site neutral payment

policy for hospital outpatient departments and ambulatory surgical centers; (3) advocates for the use of valid and reliable data in the development of any payment methodology for the provision of ambulatory services; (4) advocates that in place of the Consumer Price Index for all Urban Consumers (CPI-U), CMS use the hospital market basket index to annually update ambulatory surgical center payment rates; (5) encourages the use of CPT codes across all sites-of-service as the only acceptable approach to payment methodology; and (6) will join other interested organizations and lobby for any needed changes in existing and proposed regulations affecting payment for ambulatory surgical centers to assure a fair rate of reimbursement for ambulatory surgery.
Citation: Sub. Res. 104, A-98; Reaffirmation I-98; Appended: CMS Rep. 7, A-99; Reaffirmation A-00; Reaffirmation I-03; Reaffirmation A-11; Reaffirmed: CMS Rep. 3, A-13; Reaffirmed: Sub. Res. 104, A-14; Reaffirmed: Res. 116, A-14; Modified: CMS Rep. 3, A-14; Reaffirmation A-14; Reaffirmation A-15

Appropriate Payment Level Differences by Place and Type of Service D-330.997
1. Our AMA encourages CMS to: (A) define Medicare services consistently across settings and, in particular, to avoid the use of diagnosis codes in determining Medicare payments to hospital outpatient departments and other ambulatory settings; and (B) adopt payment methodology for hospital outpatient departments and ambulatory surgical centers that will assist in leveling the playing field across all sites-of-service. If necessary, the AMA should consider seeking a legislative remedy to the payment disparities between hospital outpatient departments and ambulatory surgical centers.
2. Our AMA will continue to encourage the CMS to collect data on the frequency, type and cost of services furnished in off-campus, provider-based departments.
Citation: CMS Rep. 7, A-99; Reaffirmation I-03; Reaffirmed: CMS Rep. 3, A-13; Reaffirmed: CMS Rep. 4, A-13; Appended: CMS Rep. 3, A-14; Reaffirmed: Sub. Res. 104, A-14; Reaffirmation A-14; Reaffirmation A-15

Offsetting the Costs of Providing Uncompensated Care H-160.923
Our AMA: (1) supports the transitional redistribution of disproportionate share hospital (DSH) payments for use in subsidizing private health insurance coverage for the uninsured;(2) supports the use of innovative federal- or state-based projects that are not budget neutral for the purpose of supporting physicians that treat large numbers of uninsured patients, as well as EMTALA-directed care; and (3) encourages public and private sector researchers to utilize data collection methodologies that accurately reflect the amount of uncompensated care (including both bad debt and charity care) provided by physicians.
Citation: CMS Rep. 8, A-05; Reaffirmation A-07; Modified: CMS Rep. 01, A-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 818
(I-17)

Introduced by: Utah

Subject: On-Call and Emergency Services Pay

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, The number of patients seen on-call and in Emergency Departments who do not have insurance is large and likely to increase; and

Whereas, It is essential for physicians working on-call and in EDs to have access to medical and surgical specialists to deal appropriately with patients and their medical and surgical problems; and

Whereas, To be able to respond to the on-call and ED requests, a physician who is on-call is prohibited from participating in any activity that might make him/her unable to meet on-call or ED requests for service; and

Whereas, Some, but not all specialties, that need to be available on-call or to the ED currently receive compensation which reimburses them to some degree for their availability or service; and

Whereas, Some medical and surgical specialists are also felt to be essential and available, but are not reimbursed for the time that they are required to be available; therefore be it

RESOLVED, That our American Medical Association amend Policy H-130.948, "On-Call Physicians," by addition to read as follows:

H-130.948 On-Call Physicians
Our AMA:
(1) strongly encourages physicians and hospitals to work collaboratively to develop solutions based on adequate compensation or other appropriate incentives as the preferred method of ensuring on-call coverage and will monitor and oppose any state legislative or regulatory efforts mandating emergency room on-call coverage as a requirement for medical staff privileges and state licensure that are not supported by the state medical association;
(2) advocates that physician on-call coverage for emergency departments be guided by the following principles:
(a) The hospital and physicians should jointly share the responsibility for the provision of care of emergency department patients.
(b) Every hospital that provides emergency services should maintain policies to ensure appropriate on-call coverage of the emergency department by medical staff specialists that are available for consultation and treatment of patients.
(c) The organization and function of on-call services should be determined through hospital policy and medical staff by-laws, and include methods for monitoring and assuring appropriate on-call performance.

(d) Physicians should be provided adequate compensation for being available and providing on-call and emergency services.
~~(d)~~ (e) Hospital medical staff by-laws and emergency department policies regarding on-call physicians' responsibilities must be consistent with Emergency Medical Treatment and Active Labor Act (EMTALA) requirements.
~~(e)~~ (f) Medical staffs should determine and adopt protocols for appropriate, fair, and responsible medical staff on-call coverage.
~~(f)~~ (g) Hospitals with specialized emergency care capabilities need to have a means to ensure medical staff responsibility for patient transfer acceptance and care.
~~(g)~~ (h) Hospitals that lack the staff to provide on-call coverage for a particular specialty should have a plan that specifies how such care will be obtained.
~~(h)~~ (i) The decision to operate or close an emergency department should be made jointly by the hospital and medical staff;
(3) supports the enforcement of existing laws and regulations that require physicians under contract with health plans to be adequately compensated for emergency services provided to the health plans' enrollees; and
(4) supports the enactment of legislation that would require health plans to adequately compensate out-of-plan physicians for emergency services provided to the health plans' enrollees or be subject to significant fines similar to the civil monetary penalties that can be imposed on hospitals and physicians for violation of EMTALA (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA develop and make available policy guidance for physicians to negotiate with hospital medical staffs to support physician compensation for on call and emergency services. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 10/12/17

RELEVANT AMA POLICY

On-Call Physicians H-130.948
Our AMA:
(1) strongly encourages physicians and hospitals to work collaboratively to develop solutions based on adequate compensation or other appropriate incentives as the preferred method of ensuring on-call coverage and will monitor and oppose any state legislative or regulatory efforts mandating emergency room on-call coverage as a requirement for medical staff privileges and state licensure that are not supported by the state medical association;
(2) advocates that physician on-call coverage for emergency departments be guided by the following principles: (a) The hospital and physicians should jointly share the responsibility for the provision of care of emergency department patients. (b) Every hospital that provides emergency services should maintain policies to ensure appropriate on-call coverage of the emergency department by medical staff specialists that are available for consultation and treatment of patients. (c) The organization and function of on-call services should be determined through hospital policy and medical staff by-laws, and include methods for monitoring and assuring appropriate on-call performance.
(d) Hospital medical staff by-laws and emergency department policies regarding on-call physicians responsibilities must be consistent with Emergency Medical Treatment and Active Labor Act (EMTALA) requirements. (e) Medical staffs should determine and adopt protocols for appropriate, fair, and responsible medical staff on-call coverage. (f) Hospitals with specialized emergency care capabilities need to have a means to ensure medical staff responsibility for patient transfer acceptance and care. (g) Hospitals that lack the staff to provide on-call coverage for a particular specialty should have a plan that specifies how such care will be obtained. (h) The decision to operate or close an emergency department should be made jointly by the hospital and medical staff;
(3) supports the enforcement of existing laws and regulations that require physicians under contract with health plans to be adequately compensated for emergency services provided to the health plans' enrollees; and
(4) supports the enactment of legislation that would require health plans to adequately compensate out-of-plan physicians for emergency services provided to the health plans' enrollees or be subject to significant fines similar to the civil monetary penalties that can be imposed on hospitals and physicians for violation of EMTALA.
Citation: CMS Rep. 3, I-99; Reaffirmation A-00; Modified: Sub. Res. 217, I-00; Reaffirmation I-01; Reaffirmation A-07; Appended and Reaffirmed: CMS Rep. 1, I-09

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 819
(I-17)

Introduced by:	American College of Rheumatology American Academy of Allergy, Asthma & Immunology Infectious Diseases Society of America Georgia, District of Columbia, New Jersey
Subject:	Consultation Codes and Private Payers
Referred to:	Reference Committee J (Peter C. Amadio, MD, Chair)

Whereas, Some commercial insurance companies may be considering or proposing discontinuation of payment for consultation codes; and

Whereas, When providing a consultation a physician must often review substantial prior documentation; refine the differential diagnosis; recommend diagnostic and/or therapeutic options; educate the patient regarding diagnostic and other considerations, prognosis and treatment options; and coordinate next steps with the patient's often myriad other providers; and

Whereas, Failing to acknowledge the difference in work between a consultation and the relative simplicity of assuming the care of a patient with a known diagnosis is misguided and will predictably limit the ability of providers to consult on complex cases; and

Whereas, Discontinuation of payment for consultation codes could result in another barrier to patient care by dissuading usual coordination of care, as the additional work that goes into providing a consultation and coordinating care amongst other treating physicians would not be properly recognized; and

Whereas, When the Centers for Medicare and Medicaid Services discontinued payment for consultation codes in 2010, the medical community raised significant concerns because in its decision the agency failed to recognize the expertise and additional collaboration that is reflected in the use of consultation codes; and

Whereas, Commercial insurance entities should provide alternative provider outreach and education on coding errors rather than eliminate important codes such as consultation codes; therefore be it

RESOLVED, That our American Medical Association proactively engage and advocate with any commercial insurance company that discontinues payment for consultation codes or that is proposing to or considering eliminating payment for such codes, requesting that the company reconsider the policy change (Directive to Take Action); and be it further

RESOLVED, Where a reason given by an insurance company for policy change to discontinue payment of consultation codes includes purported coding errors or abuses, that our AMA request the company carry out coding education and outreach to physicians on consultation codes rather than discontinue payment for the codes, and call for release of de-identified data from the company related to purported coding issues in order to help facilitate potential education by physician societies. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 10/12/17

RELEVANT AMA POLICY

Medicare's Proposal to Eliminate Payments for Consultation Service Codes D-70.953
1. Our American Medical Association opposes all public and private payer efforts to eliminate payments for inpatient and outpatient consultation service codes, and supports legislation to overturn recent Center for Medicare & Medicaid Services? (CMS) action to eliminate consultation codes. 2. Our AMA will work with CMS and interested physician groups through the CPT Editorial Panel to address all concerns with billing consultation services either through revision or replacement of the current code sets or by some other means. 3. Our AMA will, at the conclusion of the CPT Editorial Panel's work to address concerns with billing consultation services, work with CMS and interested physician groups to engage in an extensive education campaign regarding appropriate billing for consultation services. 4. Our AMA will: (a) work with the Centers for Medicare & Medicaid Services to consider a two-year moratorium on RAC audit claims based on three-year rule violations for E/M services previously paid for as consultations; and (b) pursue Congressional action through legislation to reinstate payment for consultation codes within the Medicare Program and all other governmental programs. 5. Our AMA will petition the CMS to limit RAC reviews to less than one year from payment of claims.
Citation: Res. 807, I-09; Appended: Sub. Res. 212, I-10; Reaffirmation A-12; Appended: Res. 216, A-12; Modified: CCB/CLRPD Rep. 2, A-14; Reaffirmation: A-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 820
(I-17)

Introduced by:	American Society of Clinical Oncology College of American Pathologists
Subject:	Elimination of the Laboratory 14-Day Rule Under Medicare
Referred to:	Reference Committee J (Peter C. Amadio, MD, Chair)

Whereas, The Medicare Date of Service (DOS) policy for Clinical and Laboratory Pathology Specimens was adopted by the Centers for Medicare & Medicaid Services (CMS) in 2007, creating the Laboratory 14-Day Rule[1]; and

Whereas, The 14-Day Rule specifies that billing for "complex diagnostic laboratory services" performed on pathologic specimens collected in the hospital setting be bundled into the inpatient diagnosis-related group (DRG) or outpatient (OPPS) payments made to the hospital if ordered within 14 days of discharge[2]; and

Whereas, Payment bundling of pathologic tests, including molecular and genomic testing of cancer specimens, creates a strong disincentive to hospitals to perform or send out specialized pathologic tests during the 14-day window after discharge, leading to delays in diagnosis and therapy[3]; and

Whereas, Since the adoption of the 14-day rule in 2007 there have been a growing number of therapies that are targeted to specific somatic (tumoral) mutations and delays in molecular testing can result in delays in initiation of these effective treatments; and

Whereas, Amidst complaints from stakeholders, CMS is currently considering changes to the Medicare Outpatient Prospective Payment System (OPPS) including whether to limit or eliminate the 14-Day Rule[4,5]; therefore be it

[1] 42 CFR § 414.510
[2] Lebovic LR et al. Evaluation of the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration. Centers for Medicare & Medicaid Services. July 2016. Available at https://innovation.cms.gov/Files/reports/complexdiaglabtests-evalrpt.pdf "Affordable Care Act (Pub. L. 111-148), Section 3113(a)(2) defines the term ''complex diagnostic laboratory test'' to mean a diagnostic laboratory test—(A) that is an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay; (B) that is determined by the Secretary to be a laboratory test for which there is not an alternative test having equivalent performance characteristics; (C) which is billed using a Healthcare Common Procedure Coding System (HCPCS) code other than a not otherwise classified (NOC) code under such Coding System; (D) which is approved or cleared by the Food and Drug Administration or is covered under title XVIII of the Social Security Act; and (E) is described in section 1861(s)(3) of the Social Security Act (42 U.S.C. 1395x(s)(3))."
[3] Association of Community Cancer Centers. Delays When Ordering Molecular Tests for Inpatients Due to the CMS "14 Day" Rule. Accessed on 16 Aug 2017. Available at http://accc-cancer.org/resources/molecularTesting-LearningLabs-8.asp
[4] Centers for Medicare & Medicaid Services. CMS Proposes Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Changes for 2018, and Releases a Request for Information (CMS-1678-P). 13 Jul 2017. Available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-13.html
[5] Centers for Medicare & Medicaid Services. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. 82 Federal Register 138, 33558-33724. 20 Jul 2017. 33650-33653.

RESOLVED, That our American Medical Association actively lobby the federal government to change laboratory Date of Service rules under Medicare such that complex diagnostic laboratory services performed on pathologic specimens collected from a hospital procedure be paid separately from inpatient and outpatient bundled payments. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 10/12/17

RELEVANT AMA POLICY

Laboratory Services Contracted by a Physician H-260.998
Our AMA believes that: (1) laboratories should bill and collect from patients or third party payers for laboratory services; (2) attending physicians are entitled to fair compensation for professional services rendered; and (3) bills for laboratory services performed by attending physicians should show the location where services were rendered and a description of such services.
Citation: Sub. Res. 71, A-69; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CMS Rep. 2, I-06; Reaffirmed: CMS Rep. 01, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 821
(I-17)

Introduced by: Endocrine Society
American Association of Clinical Endocrinologists
American Society for Reproductive Medicine

Subject: Hormonal Contraception as a Preventive Service

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, The majority of women of reproductive age in the United States currently use at least one contraceptive method, with more than 99 percent having used contraception during their lifetime[1]; and

Whereas, Health care practitioners frequently prescribe hormonal contraception to treat a variety of conditions; and

Whereas, Fifty-eight percent of pill users cite non-contraceptive health benefits such as treatment for excessive menstrual bleeding, menstrual pain, and acne as reasons for using the method.[2] Hormonal contraceptives are also used to treat conditions such as Polycystic Ovary Syndrome (PCOS) and endometriosis; and

Whereas, Hormonal contraception can also reduce a woman's risk of developing ovarian and endometrial cancer[3]; and

Whereas, Hormonal contraception provides a myriad of benefits beyond the expected reproductive planning by decreasing the number of unintended pregnancies and pregnancy-related health risks such as preeclampsia, gestational diabetes, and complications of childbirth; and

Whereas, Unintended pregnancies cost American taxpayers at least $21 billion each year.[4] Nationally, 68 percent of these unintended pregnancies were paid for by public insurance programs including Medicaid, Children's Health Insurance Program, and the Indian Health Service[5]; and

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[1] Guttmacher Institute. Contraceptive Use in the United States. https://www.guttmacher.org/fact-sheet/contraceptive-useunited-states. September 2016. Accessed April 28, 2017.
[2] *Ibid.*
[3] National Institutes of Health/National Cancer Institute. Oral Contraceptives and Cancer Risk. https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oralcontraceptives- fact-sheet. Reviewed March 2012. Accessed April 28, 2017.
[4] Centers for Disease Control and Prevention. Women's Reproductive Health; 2016. https://www.cdc.gov/chronicdisease/resources/publications/aag/ pdf/2016/aag-reproductive-health.pdf. Accessed April 28, 2017.
[5] Guttmacher Institute. Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care. February 2015. https:// www.guttmacher.org/sites/default/files/report_pdf/public-costs-of-up-2010.pdf.

Whereas, For every public dollar invested in contraception, short-term Medicaid expenditures are reduced by $7.09 for the pregnancy, delivery, and early childhood care related to births from unintended pregnancies[6]; and

Whereas, Expanding access to free contraception has a positive impact on insurance costs. Estimates show that the cost to provide contraception per year ranges from $100-$600[7] while the cost for prenatal care, delivery, and newborn care averages $18,000-$28,000 under private insurance[8]; and

Whereas, 77 percent of women and 64 percent of men support increased access to no-cost hormonal contraception[9]; and

Whereas, The category of employers who can claim a moral objection to providing contraception to their employees at no-cost was broadened through the October 6, 2017 Rule, thereby taking away this preventive health benefit from a significant number of women; therefore be it

RESOLVED, That our American Medical Association advocate to rescind the 2017 Rule "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act," to ensure that all women have access to no-cost hormonal contraception. (New HOD Policy)

Fiscal Note: Modest - between $1,000 - $5,000.

Received: 10/12/17

RELEVANT AMA POLICY

Support for Access to Preventive and Reproductive Health Services H-425.969
Our AMA supports access to preventive and reproductive health services for all patients and opposes legislative and regulatory actions that utilize federal or state health care funding mechanisms to deny established and accepted medical care to any segment of the population. Citation: Sub. Res. 224, I-15

[6] Guttmacher Institute. Contraceptive Use in the United States. https://www.guttmacher.org/ fact-sheet/contraceptive-use-united-states. September 2016. Accessed April 28, 2017.
[7] Guttmacher Institute. Good for Business: Covering Contraceptive Care Without Cost-Sharing is Cost-Neutral or Even Saves Money. July 16, 2014. https://www.guttmacher.org/article/2014/07/ good-business-covering-contraceptive-care-without-cost-sharing-cost-neutral-or-even
[8] Truven Health Analytics MarketScan Study. The Cost of Having a Baby in the United States. January 2013. http://transform.childbirthconnection.org/reports/cost/
[9] Sobel L, Salganicoff A. The Future of Contraceptive Coverage. The Future of Contraceptive Coverage. http://www.kff.org/womens-health-policy/issue-brief/the-future-ofcontraceptive- coverage/. Published January 17, 2017. Accessed June 2, 2017