REPORTS OF THE COUNCIL ON MEDICAL SERVI CE

The following reports were presented by Stephen Epstein, MD, MPP, Chair:

1. NONPROFIT HOSPITAL CHARITY CARE POLICIES

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 802-I-23 REMAINDER OF THE REPORT FILED
See Policies H-155.954 and H-155.958

At the 2023 Interim Meeting, the House of Delegates referred Resolution 802. Introduced by the Medical Student Section, the resolution asked the American Medical Association (AMA) to "advocate for legislation and regulation that requires nonprofit hospitals to notify and screen all patients for financial assistance according to their own eligibility criteria prior to billing, support efforts to establish regulatory standards for nonprofit hospital financial assistance eligibility, and encourage the Centers for Medicare & Medicaid Services (CMS) to publish the charity-care-to-expense ratio and the charity-care-to-benefit ratio for hospitals listed in Medicare Cost Reports to improve transparency and compliance of charitable care and community benefit activities."

BACKGROUND

An estimated 100 million people in the United States (41 percent of adults) have debt related to unpaid medical bills, totaling between $195-220 billion.1 Of this 100 million, approximately 20 million people owe money directly to their hospital, physician, or other non-physician provider.2 The remaining 80 million people reflect those that have other debts associated with their health care (i.e., credit card debt, loans from family and friends). Medical debt is the leading cause of bankruptcy in the United States and can take many forms, including past due payments owed directly to a hospital or physician, ongoing payment plans, money owed to a bank or collections that has been assigned or sold the debt, credit card debt, and/or money borrowed from family or friends.3 Those with unaffordable medical bills are more likely to skip or delay needed care, cut back on basic household expenses, take money out of retirement or college savings, or increase credit card debt.4

Nonprofit hospitals account for 58 percent of community hospitals in the United States.5 These hospitals can be exempt from federal, state, and local taxes if they qualify as 501(c)(3) organizations as defined by the Internal Revenue Service (IRS). Seven of the ten most profitable hospitals in the United States are classified as nonprofit.6

The IRS defines "charity care" or "financial assistance" as "free or discounted health services provided to persons who meet the organization's eligibility criteria for financial assistance and are unable to pay for all or a portion of these services."7 Nonprofit hospitals must provide charity care as a condition of their tax-exempt status. The estimated value of tax exemption for nonprofit hospitals has increased from $19 billion in 2011 to $28 billion in 2020.[8] A study by Letchuman, Sunjay, et. al. published in *Health Affairs* (2022) estimated that the exemption from federal, state, and local taxes amounts to roughly $25 billion annually for nonprofit hospitals across the country.9 Similarly, in 2020, KFF found that the total estimated value of tax exemption for nonprofit hospitals was approximately $28 billion, which divided into $14.4 billion from exempted federal taxes and $13.7 billion from exempted state and local taxes. KFF further found that the $28 billion total estimated value of tax exemption exceeded the total estimated charity costs of $16 billion for these nonprofit hospitals. However, charity care is only a portion of the community benefits reported by nonprofit hospitals.10

Within the broad parameters set by government regulation, hospitals establish their own charity care policies, which vary in terms of eligibility criteria, application procedures, and the levels of charity care provided.11 In 2020, charity care represented 1.4 percent or less of operating expenses at half of all hospitals, although the level of charity care varied significantly across different facilities.12 One study showed that nonprofit hospitals allocated over 80 percent of their community benefit spending on charity care and payment shortfall from Medicaid, compared to just 12 percent on community health.13 There could be several reasons for this variation. For example, strengthening the health care safety net by providing charity care is an important community need. It is easier for hospitals to continue

investing in clinical programs rather than building infrastructure needed to address social determinants of health, or hospital accounting systems are designed to better track clinical spending, making it difficult to measure the impact of community health initiatives.14

According to a recent report by the Lown Institute, approximately 80 percent of nonprofit hospitals give back less to their communities than they receive in tax breaks. For some hospitals, this means that the shortfall was hundreds of millions of dollars a year while they made hundreds of millions of dollars in net income. The 10 hospitals with the largest fair share deficits also reported at least 100 million dollars in net income in 2021, according to the report.15 The American Hospital Association contested these findings, stating that the Lown Institute's accounting was not done fairly and selectively relies on isolated data to paint a negative picture of nonprofit hospitals and the hospital industry more generally. Specifically, the Lown Institute report does not account for Medicaid shortfall or money spent on medical research. The Lown Institute defended its findings by stating that shortfalls in government reimbursement are different from direct community benefits and hospitals typically receive private or public funds for medical research.16

INTERNAL REVENUE SERVICE (IRS) REQUIREMENTS FOR NONPROFIT HOSPITAL CHARITY CARE

Tax-exempt nonprofit hospitals operate as Section 501(c)(3) organizations, which by definition must be organized and operated exclusively for specific tax-exempt purposes and must have the following characteristics: 1) no part of their net earnings is allowed to benefit any private shareholder or individual; 2) no substantial part of their activities can consist of carrying on propaganda or otherwise attempting to influence legislation; and 3) the organization should not participate in or intervene in any political campaign on behalf of (or in opposition to) any candidate for public office.17

Additional requirements were added following the passage of the Affordable Care Act (ACA) and are codified in Section 501(r) of the Internal Revenue Code. To retain 501(c)(3) tax-exempt status, nonprofit hospitals must:

- Establish a financial assistance policy (FAP) that describes who is eligible for charity care, the level of assistance provided, and how patients can apply. The FAP must be easily accessible to patients and translated into the languages commonly spoken in the community served by the hospital.
- Cap charges to patients eligible for charity care based on fee-for-service Medicare rates, Medicaid rates, and/or commercial plan payment rates.
- Conduct a community health needs assessment every three years and adopt an implementation strategy to address those needs. Community health needs could include lowering financial barriers to health care or improving social determinants of health.
- Make reasonable efforts to determine if a patient is eligible for charity care before engaging in certain debt collection practices, including selling the patient's debt to third parties, reporting the debt to credit agencies, and taking legal action to control a patient's financial assets.

A hospital has made reasonable efforts under the following conditions:

- The hospital facility notifies the individual about the FAP before initiating any extraordinary collection actions (ECA) to obtain payment for the care and refrains from initiating such ECAs for at least 120 days from the date the hospital facility provides the first post-discharge billing statement for the care.
- In the case of an individual who submits an incomplete FAP application during the 240-day application period, the hospital facility notifies the individual about how to complete the FAP application and gives the individual a reasonable opportunity to do so.
- In the case of an individual who submits a complete FAP application during the 240-day application period, the hospital facility determines whether the individual is FAP-eligible for the care.
- Extension of the application period beyond 240 days to account for a 30-day notification window before initiating one or more ECAs to obtain payment for the care.18

Furthermore, to qualify as a 501(c)(3) tax-exempt organization, a nonprofit hospital must demonstrate that it provided benefits to a class of persons that is broad enough to benefit the community and operate to serve a public rather than a private interest. A community benefit for a nonprofit hospital is defined by Revenue Ruling 69-545 as follows: 1) operating an emergency room open to all regardless of ability to pay; 2) maintaining a board of directors drawn from the community; 3) maintaining an open medical staff policy; 4) providing hospital care for all patients able to pay, including those who pay their bills through public programs such as Medicaid and Medicare; 5) using

surplus funds to improve facilities, equipment, and patient care; and 6) using surplus funds to advance medical training, education, and research.19

Circumstances brought forth by gaps in federal regulation and weak oversight and enforcement may allow hospitals to provide low levels of charity care. Federal regulations do not currently define or set minimum standards for hospitals to determine who is eligible for charity care or the level of assistance that must be provided.20,21 The IRS requires a tax-exempt hospital to file Schedule H with its Form 990 annually to provide the public with information on its policies and activities and the community benefits that its facilities provide. IRS Schedule H categorizes community benefit spending as charity care, unreimbursed costs for providing services to patients insured by government programs (Medicare and Medicaid), subsidized health service, community health improvement services and community-benefit operations, research, health-professions education, and financial and in-kind contributions to community groups.22

According to the Government Accountability Office (GAO), the IRS does not have the authority to define specific types of services and activities that a hospital must undertake to qualify for a tax exemption. Instead, the IRS provides guidance on the types of activities that can demonstrate community benefits. The IRS allows hospitals to report spending on several categories under the community benefit umbrella on Form 990 Schedule H. One category is financial assistance that hospitals provide for eligible patients to help them pay for care. Other categories include programs to improve community health like free clinics in underserved neighborhoods, free screenings or health literacy events, donations to local groups, investments in affordable housing, amongst other things. In addition to these community-based activities, nonprofit hospitals can also report hospital-based activities as community benefits, such as the expense to train health professionals and costs for hospital-based medical research. This can lead to crossover in reporting, which could lead to hospitals receiving credit for these activities in multiple ways. For example, teaching hospitals do not subtract the indirect medical education payments they receive from Medicare from community benefit reporting, thus inflating the amount of community benefit reported. In addition, hospitals can report the cost of federally funded research as a community benefit even if the hospital did not put any of its own money into the work.23

Form 990 Schedule H solicits information inconsistently, resulting in a lack of clarity about the community benefits hospitals provide. As defined on Form 990 Schedule H, the term “community health improvement” is an “activity or program, subsidized by the health care organization, conducted, or supported for the express purpose of improving community health. Such services do not generate inpatient or outpatient revenue, although there may be a nominal patient fee or sliding scale fee for these services.” Part II of Schedule H permits hospitals to report expenditures for certain “community building” activities, which encompass physical improvements and housing, economic development, community support, environmental improvements, leadership development and training for community members, coalition building, community health improvement advocacy, workforce development, and other activities.

For some factors, the IRS explicitly directs tax-exempt hospitals to report the extent to which they have addressed them. For the other factors, the IRS provides a space for hospitals to qualitatively describe the community benefits they provide. In the GAO’s analysis of hospitals’ Form 990 Schedule H filings for tax years 2015 through 2018, it found inconsistencies in what hospitals reported in the narrative description. Therefore, reporting results in inconsistent information on many of the community benefit factors. GAO recommended that the IRS update Form 990 to ensure that the information demonstrating the community benefits a hospital is providing is clear and easily understood by Congress and the public. The IRS made minor adjustments to the form, but still allows hospitals to narratively describe the community benefits they provide which continues to lead to inconsistency among different hospitals and lacks clarity.24,25

PATIENT ELIGIBILITY FOR CHARITY CARE

Hospitals have broad flexibility to establish their own eligibility criteria for charity care, and as a result, criteria vary across hospitals. Aid at some hospitals is limited to patients below the federal poverty level (FPL), while at other hospitals, patients with incomes that are five to six times the FPL can receive assistance. One analysis of a large sample of nonprofit hospitals that used FPL to determine eligibility for free care in 2018 found that about 32 percent of the hospitals required patients to have incomes at or below 200 percent FPL or they imposed more restrictive eligibility criteria, while the remaining hospitals (68 percent) relied on higher income caps. For discounted care, about 62 percent of nonprofit hospitals in the study limited eligibility to patients with incomes at or below 400

percent FPL or used lower income levels, with the remaining 38 percent of nonprofit hospitals relying on higher income caps. Hospitals may condition free or discounted care on other criteria in addition to or in lieu of income thresholds based on FPL, such as by requiring that patients have limited assets or reside in the hospital service area or by extending eligibility to patients who are unable to afford large medical bills despite exceeding income or asset thresholds under standard eligibility pathways.26

A 2019 *Kaiser Health News* analysis of tax filings found that one half of nonprofit medical systems were billing patients with incomes low enough to qualify for charity care. Eligible patients may not receive charity care because they are unaware that charity care is available, do not know they are eligible, have difficulty finding or completing the application, are improperly denied charity care by the hospital, or choose not to apply. Applying for aid can be complicated for patients, requiring considerable personal financial information and documentation. For example, nonprofit hospitals have estimated that, of the unmanageable debt they reported in 2019, about $2.7 billion came from patients who were eligible for charity care but did not receive it.

COMMUNITY BENEFITS AND CHARITY-CARE-TO-EXPENSE RATIOS

The lack of definition for a community benefit standard and the inability of the IRS to enforce guidelines for nonprofit hospitals to remain 501(c)(3) organizations, and keep their tax-exempt status, complicates this issue further. A 2020 GAO report noted that the IRS had not revoked a hospital's nonprofit status based on providing inadequate community benefits over the prior 10 years. A study by Bai, Ge, et al. published in Health Affairs (2021) found that in aggregate, nonprofit hospitals spent $2.30 of every $100 in total expenses on charity care, which was less than government ($4.10) and for-profit ($3.80) hospitals.27 For-profit hospitals devote a similar or greater share of operating expenses to charity care than nonprofit. For-profit hospitals may have a greater willingness to provide charity care in some scenarios because they can take a tax deduction for these expenses, and it is possible that some nonprofit hospitals may not expect significant oversight of their charity care practices from government regulators.28 The discrepancy suggests that many nonprofit hospital charity care provisions are not aligned with their favorable tax treatment. Because IRS guidelines established by the ACA require nonprofit hospitals to provide charity care to eligible patients based on their self-determined criteria, there are no standard qualifications utilized to identify patients eligible for charity care. This lack of standardization is confounded by hospitals' differing definitions of charity. For example, one hospital may include Medicaid shortfall and have a much higher ratio spent on charity care than another hospital, which has a lower ratio but spends more directly on charity care. Due to this inconsistency, charity-care-to-expense ratios may not be reliable forms of comparison between hospitals.

Charity-care-to-expense ratios may also belie the community impact of hospitals, as not all spending that hospitals can claim as community benefits are meaningful for community health. The broad definition of what qualifies as a community benefit allows hospitals to include spending on items that do not directly address community health needs. For example, the largest share of community benefit spending by many nonprofit hospitals is for Medicaid shortfall. Medicaid shortfall is the difference between what Medicaid pays for the care hospitals provide and the actual costs the hospital reports.29 Some hospitals already make up for the shortfall by charging private insurers higher rates or by receiving disproportionate share hospital (DSH) payments, which are given to hospitals that serve a large population of uninsured or Medicaid patients.30

STATE REPORTING REQUIREMENTS AND OUTCOMES

State regulations vary in terms of eligibility criteria and the minimum level of assistance that must be available. State policies aimed at increasing hospital charity care provisions have either used a transparency approach or a minimum requirements approach. The transparency approach mandates hospitals' disclosure or reporting of their charity care policies, implementation plans, or expenses. Examples of states using this approach include California and New York. The minimum requirements approach requires hospitals to provide a minimum charity care amount, such as Illinois and Texas, or provide charity care to patients with incomes below a certain designated threshold, such as Washington and Oregon.31

Several states have implemented regulations intended to increase the uptake of charity care among eligible patients and to protect potentially eligible patients from certain debt collection practices. Thirteen states require hospitals to screen patients for eligibility, 16 states require hospitals to notify patients they may be eligible for charity care prior to collecting payment or in every notification about collections, and eight states regulate procedures for patients to appeal denials of charity care.32

A recent study by Zare, et al. examined the association between state reporting requirements and community benefit spending by nonprofit hospitals. Nonprofit hospitals in states that required reporting spent a higher percentage of total hospital expenditures on community benefits compared to states without these requirements. A similar association between the percentage of charity care and total hospital expenditures was found.33

Studies have shown that some nonprofit hospitals spend only a small portion of their community benefit spending on services that help the community and a much greater percentage on services that benefit the hospital. A study conducted in 2018 by Singh et al. found that when states adopted multiple community benefit and charity care regulations, hospital community benefit spending increased. Other studies have found a positive association between state regulations on free and discounted care, the amount of charity care, and resource allocation decisions.34

Twenty-eight states have passed legislation requiring nonprofit hospitals to report data on community benefits and charity care. Nonprofit hospitals in states with reporting requirements spent on average 9.1 percent of total hospital expenditures on 17 distinct types of community benefits, which was an average of $32.9 million. Hospitals in states without reporting requirements spent approximately 7.7 percent of their total hospital expenditures on community benefits, which was an average of $17.8 million. After excluding Medicaid shortfall, hospital spending reduced to 5.5 percent ($20.7 million) in states with reporting requirements and 4.3 percent ($9.7 million) in states without reporting requirements. Charity care provision averaged 2.3 percent of total hospital expense ($6.7 million) in states with requirements and 1.5 percent ($3.6 million) in states without requirements. The top four community benefits reported across all types of states were Medicaid shortfall, charity care, education, and non-means-tested health services such as qualifying inpatient programs (e.g., neonatal intensive care and inpatient psychiatric units) and outpatient programs (home health programs). Nonprofit hospitals in states with reporting requirements spent 36.6 percent on Medicaid shortfall, 20 percent on charity care, 16.8 percent on education, and 8.9 percent on non-means-tested health services. Nonprofit hospitals in states without community benefit requirements spent a higher percentage on Medicaid shortfall (44.8 percent) and charity care (22.8 percent), and a lower percentage on education (11.8 percent), and non-means-tested health services (9.8 percent).35

Most recently, CMS approved a North Carolina plan that will award additional Medicaid funds to the state in exchange for forgiving the medical debt of two million people, potentially alleviating four billion dollars in medical debt.36 It will cover Medicaid recipients and individuals not enrolled in Medicaid with incomes at or below at least 350 percent of the FPL ($109,200 for a family of four), or for whom total debt exceeds five percent of annual income. Hospitals receiving the extra funds will have to agree to discount medical bills on a sliding scale for patients with incomes at or below 300 percent of the FPL, or $93,600, and automatically enroll people into financial assistance (i.e., charity care). Finally, for individuals whose income is at or below 350 percent of the FPL, hospitals must agree to not sell their medical debt to debt collectors.37

AMA POLICY

Policy H-155.958 states that the AMA encourages hospitals to adopt, implement, monitor, and publicize policies on patient discounts, charity care, and fair billing and collection practices, and make access to those programs readily available to eligible patients.

Policy H-160.923 states that the AMA: (1) supports the transitional redistribution of 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.

DISCUSSION

Nonprofit hospitals make up most hospitals in the United States and are exempt from federal, state, and local taxes as qualified 501(c)(3) organizations. This determination results in billions of dollars of tax savings annually for these hospitals. As a condition of their tax-exempt status, nonprofit hospitals must provide charity care. Nonprofit hospitals establish their own charity care guidelines within broad parameters of government regulation, resulting in many hospitals having different terms of eligibility, application procedures, and programs or services. A patient may

qualify for aid at one hospital, but not at a hospital across town. Often, the application process is not clear and requires patients to complete onerous paperwork and submit personal financial records, discouraging patients from completing financial aid applications. In some cases, patients are not screened by their hospital or physician's office prior to being billed for a service. Therefore, patients who may be eligible for financial assistance may end up getting billed for services they are unable to pay. As a result, patients may accrue medical debt that is sent to collections, beginning a waterfall of associated consequences. In addition, if hospitals were more transparent about their charity care policies, patients would be able to make more informed health care decisions based on charity care coverage.

Some hospitals have routinely engaged in suing their patients over unpaid bills. For instance, the University of Virginia Health System sued more than 36,000 patients over medical debt. It halted the practice after exposure by the media caused public outrage and, in 2021, announced it would cancel all ongoing lawsuits against households with incomes below 400 percent of the FPL.38 Even amidst the public health crisis related to COVID-19, hospitals continued to sue over debt.39 A Yale study found that nonprofit hospitals were more likely to sue for medical bills than for-profit hospitals, with the top 10 percent of hospitals filing more than 40 percent of all lawsuits from 2014-2018.40

The IRS may not have the authority to define specific types of services a hospital must provide to retain their tax-exempt status, but it could increase enforcement on nonprofit hospitals that provide little to no community benefits. According to the GAO, the IRS has not revoked a hospital's tax-exempt status for failing to provide adequate charity care since 2010. Given that there are no federal regulations defining minimum standards for benefits offered, there is considerable leeway available for nonprofit hospitals and the level of charity care they provide to retain their tax-exempt status. Therefore, increased IRS enforcement would more effectively compel hospitals to abide by charity care regulations by applying more force. In addition, a standardized definition of charity care would aid in providing clear guidelines by which nonprofit hospitals must abide by.

While charity-care-to-expense ratios can be reported based on the amount spent on charity care by nonprofit, for-profit, and government hospitals, those comparisons are limited, as there are many factors that go into determining how much each type of hospital spends on charity care and what qualifies as charity care in the area where the hospital is located. For these measurements to be useful, common definitions and federal regulations would need to be established, which seems unlikely, given the lack of oversight and enforcement by the IRS.

Some states require minimum levels of charity care and other states require nonprofit hospitals to report data on the charity care they provide. Studies have shown that when states adopted regulations to track nonprofit charity care, hospital spending on community benefits increased. More than half of states require all, or a subset of all hospitals, to extend eligibility to certain groups of people. Among those states, 11 broadly extend minimum standards to for-profit, nonprofit, and government hospitals.41 In addition, 19 states and the District of Columbia fill the gaps in federal law by setting standards for the provision of financial assistance. Some states require hospitals to provide an unspecified amount of financial assistance to people with incomes under a specific threshold (e.g., under 100 percent FPL in Florida; under 400 percent FPL in California), while others require hospitals to provide free care for people with incomes below certain thresholds (e.g., under 150 percent FPL in Maine; under 250 percent FPL in Vermont).42 In July 2024, CMS approved a North Carolina plan that will give additional Medicaid funds to hospitals in exchange for forgiving the medical debt of two million people. The plan will alleviate almost four billion dollars in existing medical debt dating back to 2014 and will cover Medicaid enrolled recipients and those not enrolled in Medicaid with incomes at or below at least 350 percent of FPL, or for whom total debt exceeds five percent of total income.43 A sliding scale has also been agreed upon to discount medical bills for patients at or below 300 percent of FPL.44

Certain states have passed laws to institute stricter requirements for screening and to remove barriers related to the application process. Maryland, for example, began requiring hospitals to consider patients already enrolled in financial assistance programs as "presumptively eligible," which means automatic eligibility without applying.45 Illinois, in addition, has had a similar requirement since 2014 and North Carolina, as part of its 2024 plan, automatically enrolls patients in financial assistance.46 Beyond this, five states require hospitals to use a state-developed uniform application form to make it easier for community-based organizations to assist patients.47

There are several shortcomings with enforcement and regulation of nonprofit community hospitals, including lack of patient screening prior to billing and lack of enforcement and regulation by the IRS. The Council recommends that

the AMA support efforts to increase patient screening prior to billing and prior to sending past due bills to collections, in addition to supporting expansion and oversight by the IRS. Additionally, the Council recommends reaffirming Policy H-155.958 which states that the AMA will encourage hospitals to adopt, publicize, and implement policies on charity care and other fair billing and collection processes.

RECOMMENDATIONS

The Council on Medical Service recommends that the following recommendations be adopted in lieu of Resolution 802-I-23, and the remainder of the report be filed:

1) That our American Medical Association (AMA) advocate that all nonprofit hospitals be required to screen patients for charity care eligibility and other financial assistance program eligibility-prior to billing.
2) That our AMA advocate to encourage debt collectors to ensure a patient has been screened for financial assistance eligibility before pursuing that patient for outstanding debt, provide an appeals process for those patients not screened previously or deemed ineligible, and require the hospital to reassume the debt account if an appeal is successful.
3) That our AMA advocate for the development of minimum standards for nonprofit hospital financial assistance eligibility programs which are publicly accessible.
4) That our AMA advocate for a standardized definition of what is considered a "community benefit" when evaluating community health improvement activities.
5) That our AMA advocate for the development of a transparent, publicly available, standardized data set on community benefit including consideration of charity care-to-expense ratios.
6) That our AMA advocate for the expansion of governmental oversight of nonprofit hospitals and enforcement of federal and/or state guidelines and standards for community benefit requirements including the ability to enact penalties and/or loss of tax-exempt status.
7) That our AMA reaffirm existing Policy H-155.958, which states that the AMA will encourage hospitals to adopt, implement, monitor, and publicize policies on patient discounts, charity care, and fair billing and collection practices and make access to those programs readily available to eligible patients.

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40 Zack Cooper, James Han, and Neale Mahoney, "Hospital Lawsuits Over Unpaid Bills Increased By 37 Percent In Wisconsin From 2001 To 2018," *Health Affairs* 40 (12) (2021): 1830–1835, available at https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01130.
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43 *Supra.* Note 38.
44 *Supra.* Note 38.
45 *Supra.* Note 44.
46 *Supra.* Note 38.
47 *Supra.* Note 44.

Council on Medical Service Report 1-I-24
Nonprofit Hospital Charity Care Policies
Policy Appendix

Appropriate Hospital Charges H-155.958
Our AMA encourages hospitals to adopt, implement, monitor and publicize policies on patient discounts, charity care, and fair billing and collection practices, and make access to those programs readily available to eligible patients.
(CMS Rep. 4, A-09; Reaffirmed in lieu of: Res. 213, I-17)

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.
(CMS Rep. 8, A-05; Reaffirmation: A-07; Modified: CMS Rep. 01, A-17)

2. UNIFIED FINANCING HEALTH CARE SYSTEM

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 818-I-23, RESOLVE TWO REMAINDER OF REPORT FILED
See Policies D-165.94 and H-165.838

At the 2023 Interim Meeting, the House of Delegates (HOD) referred the second resolve clause of Resolution 818 and asked the American Medical Association (AMA) to "support a national unified financing health care system that meets the principles of choice, freedom and sustainability of practice, and universal access to quality care for patients." The Board of Trustees assigned this item to the Council on Medical Service for a report back to the HOD at the 2024 Interim Meeting. Relatedly, the HOD voted to not adopt the first resolve clause of Resolution 818-I-23, which would have directed our AMA to remove opposition to single payer health care delivery systems from its policy, and instead evaluate all health care system reform proposals based on our stated principles as in AMA policy.

BACKGROUND

Resolution 818-I-23 defines unified financing as "any system of health care financing that provides uniform and universal access to health care coverage that is high quality and affordable, which can include single payer or multi-payer systems based on managed competition between private insurers and does not necessarily mean government run." Supplemental information provided by the sponsors describes unified financing as a system where all health care financing is managed, to varying levels, through a single integrated mechanism with the aim of streamlining health care funding, reducing fragmentation, enhancing efficiency, and improving access to health services. Analyses of health systems specifically labeled as unified financing models are scant in the health care literature aside from a handful of papers on Brazil's health system and a treatise exploring state-level transformational health reform by the Healthy California for All Commission. This Commission was established by a 2019 state law and charged with developing a plan for achieving a unified financing system in California that could include, among other options, a single payer system. The Commission's deliverable, Key Design Considerations for a Unified Health Care Financing System in California, explains unified financing as a "statewide system to arrange, pay for, and assure health care in which all Californians will be entitled to receive a standard package of health care services; entitlement will not vary by age, employment status, disability status, income, immigration status, or other characteristics; and distinctions among Medicare, Medi-Cal, employer-sponsored insurance, and individual market coverage will be eliminated."1 A *Health Affairs* paper authored by two California Commission members describes unified financing as a type of single payer system "that pools all sources of financing, public and private, into one source to finance a unified benefit package for everyone."[2] For the purposes of this report, the Council defines unified financing as a health care delivery system that pools funding sources to pay for universal coverage of a standard benefits package that is made available to everyone, regardless of age, employment status, and income. A potential role for health plans or other intermediaries distinguishes unified financing from single payer systems, which are usually government-run; however, single payer is a type of unified financing. Unified financing also includes multi-payer systems in which a single fund coordinates contributions from various sources while maintaining a standardized approach to benefits and coverage. Interestingly, unified financing can co-exist with supplemental insurance markets or private markets that operate independently, just as substitutive or supplemental private health insurance is available in many countries with unified financing—including single payer—systems. In this country, there has been no serious movement toward unified financing at the federal level and consideration of Medicare-for-All-type proposals has largely stalled; accordingly, this report focuses primarily on California's efforts to implement unified financing reforms.

Because the path towards unified financing in California is still in its early stages, uncertainties about its potential design and implementation remain, including the mechanisms through which or the levels at which physicians, hospitals, and other providers would be paid for their services; the sources of funding that will finance the system; the role (if any) of private health plans; and methods for controlling health care spending, which would be integral to the model's sustainability. According to the Commission, "a threshold issue for California involves securing federal permissions to redirect and consolidate existing federal funding for Medicaid, Medicare, and Affordable Care Act (ACA) advance premium tax credits within a state unified financing system."3 Furthermore, the reform's sustainability would largely depend on the ability of the state to maintain adequate funding levels and could potentially necessitate new or higher taxes.[4] In October 2023, the California state legislature enacted SB 770, which endorsed the Commission's recommendations for a unified financing system and directed the Secretary of the California Health and Human Services agency to "pursue waiver discussions with the federal government with the objective of a unified health care financing system that incorporates specified features and objectives, including, among others, a comprehensive package of medical, behavioral health, pharmaceutical, dental, and vision benefits, and the absence of cost sharing for essential services and treatments."5 Updates regarding the need for specific waivers or a timeline for formal waiver applications had not been published at the time this report was written.

At the federal level, unified financing could be implemented through a Medicare-for-All approach, in which eligibility for Medicare is extended to all Americans in a single payer system that replaces employer-sponsored insurance, individual market coverage, and most existing public programs, including Medicaid and Children's Health Insurance Program (CHIP). The Medicare-for-All approach was addressed by the Council in Council Report 2-A-19 and in other reports supporting improvements to the ACA and policies targeting the remaining uninsured. Longstanding AMA policy opposing single-payer systems has been periodically considered by the HOD and was kept in place most recently just a year ago. As the Council has consistently noted, focusing AMA efforts on improving the ACA instead of abandoning it helps promote physician practice viability by maintaining a robust

payer mix. Additional concerns about a Medicare-for-All approach include the enormous cost related to implementing such a system and how possible pay-fors would impact patients and physicians.

Some proponents of unified financing also maintain that the model could be implemented by merging employer-sponsored and individual insurance markets and harmonizing their subsidy systems. A Council report presented at the 2024 Annual Meeting addressed this issue and recommended incrementally lowering the ACA affordability firewall so that more workers who have access to employer-sponsored insurance would be eligible to purchase subsidized ACA plans. However, the HOD referred this report back to the Council for further study, in part because of concerns about its potential impact on payer mix and physician practice sustainability. An updated report will be presented by the Council at the 2025 Annual Meeting.

International Unified Financing Models

As noted in Key Design Considerations for a Unified Health Care Financing System in California, a range of unified financing approaches—including single payer systems and mixed models—have been used internationally to achieve universal coverage and access to a standardized set of health services. Under Canada's single payer system, there is no national standardized benefits package; instead, Canadian provinces and territories make most public coverage decisions and administer universal health insurance programs within their jurisdictions. As a result, coverage for services that are not federally mandated (e.g., outpatient prescription drugs and mental health, dental, and vision services) may vary across provinces and territories, most of which provide some level of prescription drug coverage for individuals lacking supplemental private coverage.6 Two-thirds of Canadians have supplemental private insurance—paid for mostly by employers—that covers vision and dental care, outpatient prescription drugs, private hospital rooms, and other services not covered by the publicly-funded plan.7

In addition to Australia's public system, which is funded by general taxation and an income-based tax and covers most hospital and physician services at no cost, patients can purchase private health insurance that facilitates access—at a cost—to private hospitals and specialists and other services not covered by the public system.8

Brazil's health system, known as SUS (Sistema Único de Saúde), is decentralized such that the administration and delivery of care is managed at the municipal or state level. Under SUS, which is financed by taxes and contributions from federal, state, and municipal governments, all residents and visitors can access primary, specialty, mental health, and hospital services free of charge and without cost-sharing. Almost a quarter of the population also enrolls in private plans, some of which have their own health facilities, to circumvent delays in accessing care under SUS.9

The United Kingdom's (UK) health care system is more centralized; the government-administered National Health Service (NHS), which is funded by general taxation, provides mostly free health care to its residents. NHS owns public hospitals in the UK and pays the salaries of most physicians, nurses, and other care providers and, notably, NHS physicians report high levels of stress and burnout due to staffing shortages and dissatisfaction with pay.10 As in other countries, more than 10 percent of people in the UK also have private health insurance policies that they either purchase or obtain through an employer. This private coverage provides quicker access to care, greater choice of specialists and hospitals, and amenities for elective hospital procedures but does not include general, emergency, maternity, or mental health care services which are provided by the NHS.11

Government plays a lesser role in Germany's universal multi-payer health system, where health insurance is mandatory and provided through either statutory health insurance—administered by competing nonprofit plans known as sickness funds—or substitutive private coverage that individuals can opt into if they make more than €69,300 per year. Health care is financed by mandatory contributions (from employers and workers) imposed as a percentage of wages, which are pooled into a central health fund and reallocated to the sickness funds. Individuals purchasing substitutive private coverage pay risk-adjusted premiums that are determined at the time of enrollment. Although government subsidies are not available to purchase substitutive insurance, these private plans remain attractive, especially to young people, because they may include a broader range of services and lower premiums.12

In the Netherlands, all residents must purchase statutory insurance from private health insurers and most people (84 percent) also purchase supplementary insurance that covers dental and vision care and other services not covered by the statutory plan. Statutory insurance is financed through a combination of a nationally defined income tax, government grants for those under 18 years of age, and community-rated premiums set by each insurer. Such contributions are collected centrally and allocated to insurers according to a risk-based capitation formula. Because supplemental private insurance premiums are not regulated, plans can screen for risks. Interestingly, almost all

individuals purchase voluntary supplemental coverage from the same insurer that provides their statutory health insurance.13

In its 2017 report on health care financing models around the world, the Council identified both advantages and disadvantages of each of the models studied. In that report, the Council found that the diversity of health care financing models represented different country-to-country priorities, societal beliefs, and acceptable trade-offs related to the level of coverage achieved by the financing model; individual tax burdens; and levels of government regulation, including of health care prices. The Council further found that some financing models were tied to increased government regulation of prices and budgets across the health system, which was perceived as undermining the free market principles long supported by the AMA, and that countries with such systems, including single payer models, tend to have higher rates of taxation and social insurance contributions.

The U.S. is unique among high-income countries in that it lacks a publicly financed system of universal health care. Instead, our pluralistic system incorporates multiple financing models that include a mix of public (e.g., Medicare, financed by federal taxes, a mandatory payroll tax, and individual premiums; and Medicaid and CHIP, jointly financed by federal and state tax revenues) and private (e.g. employment-based insurance, paid for by employers and employees; or plans purchased by individuals, often federally subsidized, on an ACA exchange) options. Although patients enrolled in publicly financed health systems like Medicaid may incur fewer cost-sharing expenses, they may also experience access challenges, lengthier wait times, and/or delayed or lack of access to costly innovative services and therapeutics. The private insurance system in this country reflects free market principles and embraces choice but may be more costly for some patients (and employers), thereby raising equity concerns.14

As stated in Council Report 2-A-17, approaches to paying physicians and other providers vary by country and are not wholly dependent on a country's health care financing model. Physicians can be salaried or be paid via fee-for-service or capitation, with fee schedules set by national, regional, or local health authorities, negotiated between national medical societies or trade unions and the government, or negotiated/set by sickness funds or health plans. Hospital financing can vary but generally depends on whether hospitals are public, private, nonprofit, or for-profit. Public hospitals may operate under a global budget determined by the responsible health authority, or receive a majority of their funding from national, regional, or local governments.

While the U.S. surpasses other countries when it comes to health spending, it underperforms on some metrics related to health outcomes. Americans tend to be greater consumers of medical technology and pharmaceuticals and often pay more for care in our market-based system. As noted in Council Report 2-A-17, although many governments across the world finance universal health care, there may be lengthy wait times to see physicians in some countries or an inability to access procedures or innovative therapies that can be obtained in the U.S.

Potential Benefits of Unified Financing

The California Commission's report, Key Design Considerations for a Unified Health Care Financing System in California, outlines many potential benefits of unified financing systems. The report notes that the existing fragmented financing system is administratively burdensome; lacks accountability for quality, costs, and equity; and can lead to coverage gaps for people experiencing job or life changes. According to the report, unified financing would allow the state to achieve notable health goals related to:

- Universality, since unified financing creates universal coverage;
- Improved equity, by eliminating differences in coverage between employer-sponsored insurance, Medicare, Medicaid, nongroup marketplace plans, and the uninsured;
- Affordability, since monthly premiums would no longer be paid, and long-term services and supports and dental services would be covered;
- Access, since uninsurance and underinsurance would be eliminated, and
- Quality, due to the new system being more uniform, which would facilitate quality improvements.15

Although it is possible to dispute the report's assertions that unified financing will improve health care quality and access (especially if physician and other provider payments are decreased), unified financing could streamline health care funding and lessen the fragmentation of the existing system, thereby potentially giving rise to a range of benefits, including increased equity and transparency as well as decreased administrative burdens related to the standardization of billing, prior authorization, and other insurance-related expenses, which could produce cost

savings for physicians. Additional administrative costs, related to brokers, pharmacy benefit managers, and other middlemen, could also be reduced or eliminated under unified financing.16 Reduced fragmentation should theoretically result in a system that is less administratively complex for patients to navigate, and if all physicians and hospitals are covered under unified financing, provider networks would be eliminated. Importantly, a unified financing health system would also eliminate insurance churn and reduce gaps in coverage that often occur when individuals, for a variety of reasons, switch coverage types (for example between Medicaid and ESI or ESI and ACA marketplace plans). In principle, universal coverage of standardized benefits should increase access to care, especially among people with lower incomes, and improved access may lead to improved health outcomes.17

In terms of design options, the Commission's report analyzed the costs of implementing unified financing under different scenarios that, for example, make direct payments to providers or use a health plan to do so; require zero cost-sharing or income-related cost-sharing; or include long term services and supports (LTSS) as it exists today or expanded LTSS services. According to the report, if federal and state funding streams remain consistent with current levels, and a payroll tax (or combination of other progressive taxes) is used to replace employer-sponsored insurance, a unified financing system would lower health care costs in year one and produce savings over time, primarily because the various scenarios assume significant savings will be incurred from decreases in drug prices as well as provider and payer administrative costs. SB 770 asserts that a unified financing system would save California more than $500 billion over 10 years.

Potential Challenges of Unified Financing

Unifying public and private payers into a single pooled fund would be immensely challenging in this country. Key Design Considerations for a Unified Health Care Financing System in California recognizes that transitioning to a unified financing system would completely upend health care financing and coverage as it exists today. As such, it is important to consider the feasibility of some of the assumptions delineated above, such as the payroll tax, which—the report states—will produce "winners and losers," since some employers will be required to pay more than others. Additionally, the report assumes that the U.S. Department of Health and Human Services (HHS) will agree to consolidate and redirect current levels of federal Medicaid, ACA, and Medicare funds to the state's new health authority that provides all Californians with the same benefits package, regardless of a person's age, income, or disability. For that to happen, all statutory and regulatory requirements stipulating that certain benefits be provided to particular populations would need to be waived and, moreover, some benefits enshrined in statute may need to be reduced or eliminated. The California Commission acknowledges that a waiver of this magnitude would be unprecedented and controversial, and that it is possible that HHS may not be authorized to approve such a model without new federal authorizing legislation.18

Both a direct payment approach, in which providers would be paid directly by the state authority, and an approach that uses health plans or other nonprofits as intermediaries, were discussed in the California Commission's report. If health plans or health systems are used as intermediaries, they would be required to offer the same benefits and cost-sharing structure, which could be perceived as antithetical to choice, which is embraced in AMA policy. Although it is not clear how physicians and other health care providers would be paid under a unified financing system, the report cites the Maryland Total Cost of Care Model, which sets global budgets for hospitals, as a potential design feature. For physicians and other outpatient providers, the Commission's report states that the "unified financing authority would either set or negotiate fee-for-service based payment rates," and that "aggregate payments to physicians would be equal to the weighted average of current Medi-Cal, Medicare, and ESI payments, minus estimated reductions in costs due to reduced billing and administrative costs." The report further states:

> *One implication of [unified financing] UF is that physicians whose patients are currently primarily covered by private insurance will receive less revenue under UF than they do under the status quo, while physicians whose patients are primarily insured by Medicare and Medi-Cal will receive an increase in revenue. The analysis assumes that, because the UF system will be the only source of third-party payment, all California physicians and other health care providers will participate in the UF system.*

Notably, the latter assumption may violate AMA policy on physician choice of practice (Policy H-385.926) and physician freedom to participate in a particular insurance plan or method of payment (Policy H-165.985). Language in SB 770 specifies that unified financing waivers should incorporate "a rate-setting process that uses Medicare rates as the starting point for the development of final rates that avoid disruptions in the health care system and expand the availability of high quality vital services by sustaining a stable, experienced, and

equitably compensated workforce."19 Still, any cuts to physician, hospital, and other provider payments under unified financing in California or any other state, or federally, could have widespread ramifications on the delivery system, physician supply, and patient access to care. As noted in the previous section, fewer administrative burdens under unified financing could lead to reductions in prior authorization and billing costs incurred by physicians producing some cost savings. However, potential payment impacts are especially concerning given that annual Medicare payment reductions and the lack of an inflationary update already threaten the viability of physician practices, add to physician's considerable burdens, and stifle innovation. Medicaid physician payment rates also remain inadequate in many states which negatively impacts patient access to certain care. At the same time, as evidenced by a 3.6 percent projected increase to the MEI in 2025, the inflationary costs associated with running a practice continue to rise while physician payments under Medicare and Medicaid are failing to keep up.

With regard to pluralism, unified financing assumes a centralization of financing while garnering potential efficiencies, which could potentially cause benefits and payment levels to coalesce into a single or tightly limited range. If this were to occur, patients and physicians would have little recourse should decisions be made to underpay for certain types of medical care or to deny or modify coverage for certain services. In turn, this could affect the adoption of newer technologies and treatments, which some insurers may cover sooner than others or with fewer or more restrictions. Under the current decentralized (pluralistic) system of competing health plans, some patients and physicians can choose not to purchase a particular insurance product, or to not be in network with those payers; however, this may not be feasible in a more centralized unified financing system. These concerns would be mitigated, however, if supplemental private plans offering different benefits become available on top of the standardized unified financing plan.

Although analyses of California's unified financing approach project cost-savings over time, it is important to point out that single payer systems have been estimated to increase federal health spending by more than 50 percent, which may not be politically palatable.20 Depending on health system design specifications, a unified financing model could necessitate increases in taxation. Additionally, as evidenced by experiences around the world, political and economic shifts can pose serious risks to the stability of unified financing systems which, if not adequately funded, experience capacity and physician shortages as well as bottlenecks that can delay medically necessary care when fiscal austerity measures are put in place. Finally, transitioning residents into a transformed health system could lead to administrative challenges, especially in the early years, similar to those experienced when the ACA was first implemented.

A Potential Feature of Unified Financing: Hospital Global Budgeting

Hospital global budgeting, which has been implemented in other countries (e.g., Canada and the Netherlands) and in U.S. jurisdictions participating in the Centers for Medicare & Medicaid's (CMS) "state total cost of care" demonstrations, was cited by the California Commission as a potential design feature under unified financing that could help control health care costs. In this country, hospitals implementing global budgeting are generally exempt from Medicare's inpatient and outpatient prospective payment systems and are instead paid predetermined, fixed annual budget amounts based on previous years' Medicare and Medicaid payment levels, adjusted for inflation and population changes. Hospitals operating under global budgeting thus experience more payment stability and predictability, since they know what they will be paid from year to year, enabling more proactive planning.[21] Hospitals can also retain some revenues by managing costs below established payment levels, which may incentivize them to provide value-based care and reduce preventable hospitalizations.

To advance hospital global budgeting in more states, CMS launched a new voluntary state total cost of care model called States Advancing All-Payer Health Equity Approaches and Development (AHEAD) in 2023. At the time this report was written, four states had signed on—Maryland, Vermont, Connecticut, and Hawaii.22 According to CMS, the AHEAD model aims to drive multi-payer alignment across more states through hospital global budgeting coupled with a primary care component. To address improvements in health equity, adjustments for social risk will be incorporated into hospital global budget payments.23

Global budgets are not new and could potentially be implemented as part of California's unified financing system. Although about half of the states attempted to regulate hospital prices in the 1970s, Maryland is the only state that has continuously embraced an all-payer approach and has been partnering with CMS to implement global hospital budgeting since 2014.24 Vermont has administered an all-payer model for accountable care organizations (ACOs) since 2017,25 the same year that Pennsylvania began implementing a rural health model that pays participating

hospitals a fixed amount prospectively, regardless of patient volume.26 These states have been able to implement such changes by participating in CMS waiver demonstrations and their experiences contributed to the design of the new AHEAD model.

Maryland's global budget is limited to hospitals; physician services provided in hospital settings and care provided outside of hospital campuses are generally excluded. Annual budgets are established by the Health Services Cost Review Commission for each hospital (excluding federal and children's hospitals, and some specialty hospitals) in the state using the previous year's budget as the base coupled with annual updates reflecting inflation and population growth. This independent state agency also sets all-payer pricing for hospital care units of service, which are used to determine a hospital's global budget amount.[27] Through its federal waivers, Maryland has committed to producing $2 billion in Medicare savings between 2019 and 2026 while improving quality and population health in the state. An evaluation of the program found that, in 2022, 41 hospitals were able to retain $1.1 billion in revenue by reducing volume while 11 hospitals surpassed the volume included in their global budgets, resulting in negative $79 million in revenue.28 From 2014 through 2018, Maryland's all-payer model resulted in $975 million in Medicare savings while reducing inpatient admissions and potentially avoidable hospitalizations.29

AMA POLICY ON HEALTH SYSTEM REFORM

The AMA continues to advocate for policies that allow physicians and patients to be able to choose from a range of public and private coverage options with the goal of providing coverage to all Americans. To achieve universal coverage, the AMA has long advocated for the promotion of individually selected and owned health insurance; the maintenance of the safety net that Medicaid and CHIP provide; and the preservation of employer-based coverage to the extent that the market demands it. Notably, the AMA's proposal for health system reform—which is grounded in AMA policies supporting pluralism, freedom of choice, freedom of practice, and universal access for patients—has been extensively debated by the HOD for more than 25 years. Based principally on recommendations developed by the Council, beginning in 1998, AMA policy has advocated for the promotion of individually selected and owned health insurance using refundable and advanceable tax credits that are inversely related to income so that patients with the lowest incomes receive the largest credits (Policies H-165.920 and H-165.865). Our policy also underscores that, in the absence of private sector reforms that would enable people with lower incomes to purchase health insurance, the AMA supports eligibility expansions of public sector programs, such as Medicaid and CHIP, with the goal of improving access to health coverage to groups that would be otherwise uninsured (Policy H-290.974).

The principles and guidelines embedded throughout the AMA's large compendium of health reform policy, which has been refined over the years as the coverage environment has evolved, form the basis by which the AMA continues to thoughtfully evaluate and engage in advocacy around a broad array of approaches to achieve universal health coverage. Since the ACA was enacted, the HOD has adopted a multitude of policies addressing how to cover the remaining uninsured and improve health care affordability, thereby ensuring that our proposal for reform continues to evolve. For example, Policy H-165.823 was amended in 2021 to address uninsured individuals who fall into the "coverage gap" as well as those ineligible for coverage due to immigration status. Policy H-290.955 was adopted in 2022 and subsequently amended in 2023 to address the unwinding of Medicaid's continuous enrollment requirement, which was the most significant nationwide coverage transition since the ACA and led to improper Medicaid disenrollments of eligible individuals in many states.

This year, the AMA's plan to cover the uninsured focuses on expanding health insurance coverage to five main population targets, which make up the nonelderly uninsured population: 1) individuals eligible for ACA premium tax credits (35 percent of the uninsured); 2) individuals eligible for Medicaid or CHIP (25 percent of the uninsured); 3) people who are ineligible for ACA premium tax credits due to an offer of "affordable" employer-provided insurance (20 percent of the uninsured); 4) individuals ineligible for coverage due to immigration status (15 percent of the uninsured); and 5) people ineligible for Medicaid because they fall into the "coverage gap" in states that have not expanded Medicaid (6 percent of the uninsured).[30] To maximize coverage and improve affordability, the following policies form the basis of the AMA proposal for reform:

- Policy H-165.824 supports improving affordability in health insurance exchanges by expanding eligibility of premium tax credits beyond 400 percent of the federal poverty level (FPL); increasing the generosity of premium tax credits; expanding eligibility for cost-sharing reductions; and increasing the size of cost-sharing reductions.

- Policy H-290.955, which was adopted in response to the Medicaid unwinding, encourages states to facilitate coverage transitions, including automatic transitions to alternate forms of coverage, including for people no longer eligible for Medicaid who are eligible for ACA marketplace plans. This policy also encourages state Medicaid agencies to implement strategies to reduce inappropriate terminations from Medicaid/CHIP for procedural reasons and provide continuity of care protections to patients transitioning to a new health plan that does not include their treating physicians. Finally, this policy supports additional strategies that respond to improper Medicaid disenrollments.
- Policy H-165.828, which is intended to help employees having difficulties affording ESI, supports lowering the threshold used to determine ESI affordability to the level at which premiums are capped for individuals with the highest incomes eligible for subsidized ACA coverage.
- Policy D-290.979 advocates that all states expand Medicaid, as authorized by the ACA.
- Policy H-165.823 advocates for a pluralistic health care system—which may include a public option—that focuses on increasing equity and access, is cost-conscious, and reduces burden on physicians. This policy establishes standards for supporting a public option and states that it shall be made available to uninsured individuals who fall into the "coverage gap" in states that do not expand Medicaid at no or nominal cost. Policy H-165.823 also directs the AMA to advocate that any federal approach to covering uninsured individuals who fall into the "coverage gap" in non-expansion states makes health insurance coverage available at no or nominal cost, with significant cost-sharing protections. Importantly, this policy supports extending eligibility to purchase ACA marketplace coverage to undocumented immigrants and Deferred Action for Childhood Arrivals recipients. Finally, Policy H-165.823 supports states and/or the federal government pursuing auto-enrollment in health insurance coverage provided it meets certain standards.
- Policies H-165.824, H-290.976, H-290.971, H-290.982 and D-290.982 support investments in outreach and enrollment assistance activities to improve coverage rates of individuals eligible for ACA financial assistance or Medicaid/CHIP.
- 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 a) 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, b) ensure and maximize patient choice of physician and private health plan, and c) include reforms that eliminate denials for pre-existing conditions.

A plethora of health reform principles are also delineated throughout the AMA's health reform policy, including Policies H-165.838, H-165.888, H-165.846, and H-165.985. Policy H-165.838 commits the AMA to achieving health reforms that include the following components:

- Health insurance coverage for all Americans;
- Insurance market reforms that expand choice of affordable coverage and eliminate denials for pre-existing conditions;
- Assurance that health care decisions will remain in the hands of patients and their physicians, not insurance companies or government officials;
- Investments and incentives for quality improvement and prevention and wellness initiatives;
- Repeal of the Medicare physician payment formula that triggers steep cuts and threaten seniors' access to care;
- Implementation of medical liability reforms to reduce the cost of defensive medicine; and
- Streamline and standardize insurance claims processing requirements to eliminate unnecessary costs and administrative burdens.

Policy H-165.888 directs the AMA to continue its efforts to ensure that health system reform proposals adhere to a range of principles regarding choice and include valid estimates of implementation costs and the identification of sources of funding, including specific types of taxation. Policy H-165.846 supports a series of principles to guide in the evaluation of health insurance coverage options, including 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. Policy H-165.985 reaffirms core AMA health reform principles, including free market competition, freedom of patients to select and change physicians or health plans, freedom of physicians to choose whom they will serve, to establish their fees at a level which they believe fairly reflect the value of their services, and to participate or not participate in a particular plan or method of payment.

The AMA also has policy addressing some of the federal waivers that would be needed for California or another state to move forward with implementing a unified financing model, including:

- Policy H-165.826, which supports the criteria outlined in Section 1332 of the ACA for the approval of State Innovation Waivers, including that the waiver must: a) provide coverage to at least a comparable number of the state's residents as would be provided absent the waiver; b) 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) provide coverage that is at least as comprehensive for the state's residents as would be provided absent the waiver; and d) not increase the federal deficit.
- Policy H-290.987, which supports the provision of state Medicaid waivers, provided they promote improving access to quality medical care; are properly funded; have sufficient physician and other provider payment levels to secure adequate access; and do not coerce physicians into participating.
- Policy H-165.829, which encourages the development of state waivers to develop and test different models for transforming employer-provided health insurance coverage, including giving employees a choice between employer-sponsored coverage and individual coverage offered through health insurance exchanges, and allowing employers to purchase or subsidize coverage for their employees on the individual exchanges.

After thoroughly reviewing the compilation of AMA health reform policies, the Council also notes that, depending on specific design features, unified financing proposals may be inconsistent with the following AMA policies:

- Policy H-165.838, under which the AMA supports health system reform alternatives that are consistent with AMA policies on pluralism, freedom of choice, and freedom of practice. This policy also states that the creation of a new single payer, government-run health care system is not in the best interest of the country and must not be part of national health system reform.
- Policy H-165.920, which affirms AMA support for pluralism of health care delivery systems and financing mechanisms in obtaining universal coverage and access to health care services.
- Policy H-165.888, which states that unfair concentration of market power of payers is detrimental to patients and physicians if patient freedom of choice or physician ability to select mode of practice is limited or denied.
- Policy H-165.985, which opposes socialized or nationalized health care and instead supports: 1) free market competition among all modes of health care delivery and financing, with the growth of any one system determined by the number of people who prefer that mode of delivery, 2) freedom of patients to select and change their physician or medical care plan, 3) freedom of physicians to choose whom they will serve, to establish their fees, and to participate in a particular insurance plan or method of payment, and 4) improved methods for financing long-term care through a combination of private and public resources.
- Policy H-165.844, which reaffirms support of pluralism, freedom of enterprise and strong opposition to a single payer system.
- Policy H-285.998, which is one of the AMA's preeminent policies addressing managed care, states that the needs of patients are best served by free market competition and free choice by physicians and patients between alternative delivery and financing systems.

DISCUSSION

Although the Council last presented a comprehensive report on health care financing models in 2017 (Council Report 2-A-17), several reports since then have enhanced AMA policy on health system reform and covering the uninsured, including:

- Council Report 2-A-18, Improving Affordability in the Health Insurance Exchanges;
- Council Report 3-A-18, Ensuring Marketplace Competition and Health Plan Choice;
- Council Report 2-A-19, Covering the Uninsured Under the AMA Proposal for Reform;
- Council Report 1-Nov-20, Options to Maximize Coverage Under the AMA Proposal for Reform;
- Council Report 3-Nov-21, Covering the Remaining Uninsured;
- Council Report 3-A-22, Preventing Coverage Losses After the Public Health Emergency Ends;
- Council Report 6-A-23, Health Care Marketplace Plan Selection; and
- Council Report 5-I-23, Medicaid Unwinding Update.

Together, these reports have established AMA policy that seeks to guarantee affordable health coverage—and timely access to quality care—for every American while embracing the organization's commitment to universal coverage, and to longstanding principles related to pluralism, choice, freedom and sustainability of practice, and

universal access to care. The compilation of health reform policy summarized in this report forms the basis by which the AMA continues to evaluate and engage in advocacy around health system reform proposals and efforts to improve the health care system for all patients and physicians. As AMA policy evolves, so too does the AMA's plan to cover the uninsured, which is updated biennially to incorporate current metrics on the uninsured and operationalize AMA priorities for improving affordability and covering the remaining uninsured.

At the 2023 Interim Meeting, the HOD voted against removing AMA opposition to single payer systems (e.g., Medicare-for-All-type proposals) from its policy while referring the second resolve of Resolution 818-I-23, which led to the Council's unified financing study and the development of this report. The Council's study of unified financing systems was limited in part by the lack of formal analyses on the impact that such models would have on patients, physicians, hospitals, medical practice, and the costs, quality, and timeliness of care in the U.S. consistent with this limitation, the Council found that discussions of this type of reform are still in the preliminary stages in this country, with California taking the lead as it explores pursuing federal waivers that would be required for the state to pool and redistribute Medicaid, Medicare, ACA, and possibly other federal dollars under a unified financing system. Even in California, the Council believes it is unclear how unified financing would work or how physicians and patients would be impacted. As more details regarding the specific features of California's plan are released, the Council will continue to explore the model's pros and cons and consider critical lessons that will be learned from the state's experience. At this time, while the Council generally finds that unified financing has potential to reduce fragmentation in our health care system, improve health equity, and eliminate insurance churn and coverage gaps, we remain strongly concerned that patients and physicians would have less choice under this model, and that physician and hospital payments may be reduced in order to lower health care costs and fund system redesign. As cautioned in this report, the Council believes that any cuts to physician or hospital payments could have widespread ramifications on the delivery system, physician supply, and patient access to care, especially given ongoing threats to practice sustainability due to longstanding inadequacies of Medicare and Medicaid payment rates.

The Council is intrigued by California's embrace of unified financing and pursuit of transformational health reform; however, we also recognize that the state is likely years away from implementing unified financing and that many uncertainties about its model's design and potential implementation remain, including how such a system would be funded, and what new taxes—payroll or otherwise—might be needed; the mechanisms through which and the levels at which physicians and hospitals would be paid; and the role (if any) of private health plans. Since no state had begun pursuing the necessary waiver applications at the time this report was written, the Council also has lingering questions about the feasibility of unified financing in the U.S., especially since federal waivers, even if approved, can be undone when Administrations change. Furthermore, it is unclear if HHS would even have the statutory authority to consolidate and redirect current levels of federal Medicare, Medicaid, and ACA funds without new federal legislation. As previously noted, there is no significant movement towards unified financing at the federal level and consideration of Medicare-for-All-type proposals has largely stalled.

Although the Council's study included international examples of unified financing systems, we emphasize that models implemented in other countries are not generalizable to the U.S. because of the existing complexities inherent to our current system. Until the aforementioned implementation issues are resolved, we believe it would be premature to recommend new AMA policy on unified financing, such as principles or guardrails that unified financing systems should incorporate (similar to the public option standards delineated in Policy H-165.823). Instead, this report summarizes the potential benefits and challenges of a unified financing model without commenting on its advisability. In order to keep abreast of new unified financing developments in California or elsewhere, the Council recommends that our AMA continue to monitor federal and state health reform proposals, including the development of state plans and/or waiver applications seeking program approval for unified financing. Consistent with California's exploration of a unified financing model and potential action in other states, the Council also recommends reaffirming Policy D-165.942, which advocates that state governments be given the freedom to develop and test different models for covering the uninsured provided that certain standards are met (e.g., patient choice of physician and private health plan must be ensured).

The Council continues to stand behind the substantial health reform policies summarized herein, which reflect the organization's commitment to achieving universal coverage by improving the current system and expanding its reach to Americans who fall within its coverage gaps. Instead of upending and fully redesigning the health system, which may be unrealistic, AMA policy builds on the foundation already in place—a pluralistic system that embraces competition and freedom of choice—to achieve the right mix of public and private coverage and expanded Medicaid options in every state. The Council has heard the argument that our policy opposing single payer systems precludes

the AMA from engaging in discussions of federal and state health reform proposals. However, we maintain that the AMA stands ready to evaluate any mature reform proposal that is introduced, no matter its structure and scope. Furthermore, the Council did not identify any gaps in existing AMA policy that need to be addressed for the AMA to continue advancing its health reform vision with Congress, the Administration, and states. Even if a moderately detailed unified financing proposal was introduced tomorrow, its provisions could be thoroughly vetted for consistency with the existing health reform policies cited in this report, such as Policy H-165.838, which upholds the AMA's commitment to achieving enactment of health system reforms that include health insurance coverage for all Americans, expand choice of affordable coverage, ensure that health care decisions remain in the hands of patients and their physicians, and are consistent with pluralism, freedom of choice, freedom of practice, and universal access.

RECOMMENDATIONS

The Council on Medical Service recommends that the following recommendations be adopted in lieu of the second resolve clause of Resolution 818-I-23, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) continue monitoring federal and state health reform proposals, including the development of state plans and/or waiver applications seeking program approval for unified financing.
2. That our AMA reaffirm Policy D-165.942, which advocates that state governments be given the freedom to develop and test different models for covering the uninsured, provided that proposed alternatives a) 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, b) ensure and maximize patient choice of physician and private health plan, and c) include reforms that eliminate denials for pre-existing conditions.
3. That our AMA reaffirm Policy H-165.838, which upholds the AMA's commitment to achieving enactment of health system reforms that include health insurance for all Americans, expand choice of affordable coverage, assure that health care decisions remain in the hands of patients and their physicians, and are consistent with pluralism, freedom of choice, freedom of practice, and universal access.

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3. TIME-LIMITED PATIENT CARE

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION: **RECOMMENDATIONS ADOPTED**
REMAINDER OF REPORT FILED
See Policies D-225.977, H-70.976, H-405.957 and H-410.945

At the June 2024 Annual Meeting, the House of Delegates adopted Resolution 705 (Policy D-450.951), which asks our AMA to "study the impacts of time-limited physician visits on patient care quality, patient satisfaction, and physician satisfaction." Testimony at the 2024 Annual Meeting regarding the resolution was supportive, highlighting a need to study this issue beyond primary care. The Council wishes to note that the core of physician time pressures is not an issue of coding, but rather one of arbitrary time-limits enacted as a result of insurer, administrative, and/or hospital system policies. Therefore, the following report will not focus on coding, but rather on the root causes and possible solutions for this issue. Additionally, this report covers the history of time-limited care and the impact of time limits on patients and physicians, highlights American Medical Association (AMA) advocacy efforts and essential policy, and presents new policy recommendations.

BACKGROUND

While time-limited physician visits are not a national standard or requirement, it is not an uncommon experience for many physicians and patients. The time limits placed on visits, typically 15-20 minutes, have largely been implemented as a result of the need to foster profitability within payment models, especially in large health care systems. When surveyed, only 14 percent of physicians indicated that they felt the time allotted for patient visits was adequate to provide patient care at the desired quality level.1 For new patient visits, health systems allowed physicians an average of 35 minutes, yet physicians reported needing nearly 46 minutes. Similarly for established patients, physicians indicated that they were allotted an average of 20 minutes but needed close to 24 minutes to satisfactorily meet the patient's needs.[2] Physicians who work in managed care and/or health maintenance organization settings tend to experience these time pressures at an elevated level compared to physicians practicing in other settings. However, pressure to maintain time-limited visits is pervasive throughout the health care system.2

Time pressures are thought to be a reflection of the health care system as a whole working to treat acute conditions rather than working preventively, and research has demonstrated that it may be impacting health care disparities. Specifically, patients who are insured through private payers tend to be allotted more time for visits than beneficiaries of public insurance or the uninsured.3 It has also been shown that Non-Hispanic Black patients had, on average, shorter visits than Non-Hispanic White patients when under the care of the same physician.[3] Additionally, patients dealing with mental health diagnoses, those with disabilities or chronic conditions, and those with limited English proficiency often need more time with their physician(s).[2,3,4] Patients who have more complex care needs and/or are at higher risk to experience adverse social determinants of health (SDOH) need more time with physicians, and this research demonstrates that they may actually be getting less.[2,3,4]

PHYSICIAN SATISFACTION

Time-limited visits have increased likely as a result of the pressure from payers, hospital systems, and practice administrators to provide short visits, in order to maximize revenue.[2,6] Physicians who report more time pressures, or the inability to complete necessary work in the allotted time, also report decreases in their overall job satisfaction.[1,9] Additionally, strict time pressures on patient visits have been linked to increases in physician stress, burnout, job dissatisfaction, and intent to leave practice.[1,5,9] Interestingly, when physicians consciously choose to ignore the time pressures, associated job satisfaction increases, despite the potential consequences from employers or management.[9] When supported by management or systems to take the necessary time with patients, physicians report better overall personal outcomes, tend to rate their workplace more positively, and are less likely to indicate they are considering leaving practice.[1,5]

With the increase in managed care arrangements, physician pressure to limit visit length seems to be intensifying.[2,3] On average, physicians report being able to spend about 18-20 minutes per visit but are strongly encouraged by administrators to limit visit time to as short as 10 minutes. These pressures have been shown to be more intense for female physicians as opposed to their male counterparts.5,6 Importantly, this pressure can also stem from low payment rates from insurers and force many physicians to maintain short visit lengths in order to ensure adequate payment.[3,4] Research justifies physician concerns that imposing time limits has negative impacts on patient care and workforce sustainability.

This issue is particularly well studied among primary care physicians (PCPs), as they often face extreme time pressures to maintain the financial viability of a practice or health system. Estimates indicate that PCPs would need to practice for 26.7 hours per day to meet the needs of an average patient panel and maintain financial viability.7 While much of the research in this area is focused on primary care, there is some research that reveals that physicians across specialties are being pressured by insurers and/or administrators to limit visit length. For example, physicians in the specialties of cardiology, oncology, and urology reported spending as little as nine minutes with patients. Averages from this study indicate that the majority of subspecialists do not spend more than 24 minutes with patients, echoing the trend seen in primary care.[7,8]

PATIENT SATISFACTION & QUALITY OF CARE

Both patients and physicians are in agreement that inappropriately short visits are not just frustrating but can negatively impact patient care and the patient-physician relationship.[1,2,9] When patients feel they have their physician's attention for an adequate amount of time to address concerns, they are more likely to report satisfaction

with the specific visit, as well as the physician, practice, or system.[4] This is particularly important as patient satisfaction has been linked to increases in patient willingness to attend appointments and comply with medical advice.[4] In order for physicians to be able to provide effective care, it is essential that patients are comfortable not only attending visits but following advice from their physician.

For patients without complex care needs and/or who are not impacted by SDOH, shorter visits may be appropriate, without any negative impact on quality of care or patient outcomes.[6] However, other research has shown poorer outcomes for all patients when visit time is restricted.[1,10] For example, among patients with chronic noncancer pain (CNCP), time pressures are linked to less effective pain management, a particular problem as patients with CNCP may be prescribed opioids in lieu of taking the time to explore other pain management options.[11] Similarly, research demonstrates that shorter visits may be linked to less appropriate antibiotic prescribing practices. Due to the time limits, physicians are unable to fully discuss treatment options with patients and may be forced to rely on the "quick fix" of prescribing antibiotics.[3] As previously mentioned, increased time pressures tend to be linked to poorer quality care. This is particularly important as a lack of comprehensive preventive care may lead to higher levels of avoidable downstream health care utilization that burdens an already overwhelmed system.[6]

MANAGEMENT STRATEGIES & OPPORTUNITIES

While the issue of time pressures and its solutions are wrought with complexity, there are some strategies that physicians may utilize to help physicians cope with this stressor. Importantly, none of these strategies are able to fix the core issue of time pressures but may assist physicians in operating in their current systems or employment settings. One of these opportunities is to utilize established management principles and strategies. Research suggests that, among others, strategies like, prioritization, limiting interruptions, and the delegation of responsibilities can assist physicians and yield higher satisfaction and lower stress.[12] Additionally, physician education around cognitive-based principles like cognitive load theory and time-management inventory allowed for physicians to implement changes in their time-management and utilize time more effectively.[13] Finally, established time-management principles, like the Lean Principles,[14] can be helpful for physicians to utilize to manage time pressures. In conjunction with or addition to time-management strategies, physicians may be able to utilize tools which could include virtual scribes, medical or ambient speech recognition, and/or artificial intelligence-based assistants.[15]

In addition to tools and strategies previously mentioned, physicians may be able to utilize collaborative strategies to manage time-pressures. First, physicians could utilize population health management (PHM), a strategy that focuses on improving population health, improving patient experience, and reducing costs. PHM relies on a collaboration between physicians, or other health care providers, social services, and public health departments.[16] Research has begun to show that the utilization of PHM may not only improve patient satisfaction, but also patient outcomes and physician satisfaction.[17,18] Some research has even suggested that PHM may work to reduce health disparities.[19] A second collaboratively-based opportunity that could be utilized by physicians to manage time pressures is medical-legal partnerships (MLPs). In these partnerships, physicians, or other health care providers, work in collaboration with legal professionals to address the legal and social needs that are harming their patient's health.[19] These partnerships can be especially helpful in dealing with time-pressures as physicians caring for patients facing SDOH often report needing more time to address the litany of complex issues their patient is facing.[6] Research has demonstrated that physicians engaged in MLPs not only have partners to rely on in addressing their patient's needs, but also report higher job satisfaction. Additionally, patients treated by physicians in MLPs have shown more positive health outcomes.[20] Not only could MLPs assist in physician time-management through delegation and collaborative teamwork, but they have also been shown to improve outcomes for both patients and physicians.[20] While none of these opportunities are a guaranteed fix, nor do they address the root cause of time pressures, physicians may wish to utilize them in order to operate within the current health care system.

AMA POLICY & ADVOCACY

AMA policy supports physician autonomy, including determination of visit length. Policy H-285.969 outlines AMA efforts to ensure that physicians are able to maintain autonomy in care arrangements or settings. Policy H-70.976 monitors attempts by the third-party payers to institute time limits on visits and discourages payers from adopting time limit policies. In addition to the policy outlining support for physician autonomy, AMA policy also highlights the importance of ensuring that physicians have the opportunity to be involved with governance structures. Specifically, Policy D-225.977 details support ensuring that employed

physicians not only have autonomy, but that opportunities for them to be involved in leadership, self-governance, and partnerships are promoted.

AMA policy also advocates for reducing physician burnout and increasing physician satisfaction. Policy D-310.968 addresses the institutional causes of physician demoralization and burnout, such as the burden of documentation requirements, inefficient workflows, and regulatory oversight. Policy H-405.948 outlines the variety of factors that cause many physicians and medical students to experience burnout. Policy H-405.972 supports an accreditation program for hospitals and systems that facilitate physician well-being. Policy H-405.957 supports the implementation of programs that are aimed to identify and manage stress and burnout in physicians and medical students.

The *AMA Joy in Medicine Health System Recognition Program* utilizes tools to enable health care systems to evaluate themselves in six competency areas toward reducing physician burnout and increasing physician well-being: (1) assessment of burnout and well-being, (2) commitment to improving workforce well-being, (3) efficiency of practice environment, (4) teamwork,
(5) supportive leadership, and (6) a supportive environment. Additionally, the AMA *Physician Well-Being Program* aims to raise awareness and advance change to reduce physician burnout and increase physician well-being by better understanding system-level factors associated with physician burnout and its consequences. Similar to the *Joy in Medicine Program*, it offers organizations a tool to assess the supportiveness of their environment as well as resources for improving or maintaining these efforts. Finally, the *AMA Steps Forward* program provides physicians with educational resources and solutions to address a number of topics, including burnout. These resources include playbooks, podcasts, webinars, toolkits, and real-world examples.

DISCUSSION

While a small body of research indicates that for some low-risk patients, time-limited visits may not negatively impact patient care, the majority of available research demonstrates that time-limited visits can be linked to a decrease in quality of care. Therefore, the Council recommends the adoption of new policy to support efforts to ensure that physicians are able to determine the length of patient care visits without undue influence from outside entities like payers, administrators, and health systems. Not only is it important that physicians have autonomy in the length of visits, but it is also important that those caring for patients with more complex issues or dealing with SDOH are able to incorporate these complexities into visit length. Therefore, the Council recommends the adoption of new AMA policy that supports efforts to ensure that patient complexities and SDOHs are factored into the calculations of the appropriate visit length.

In addition to the new policy, it is recommended that Policy H-70.976 be reaffirmed, as it monitors and seeks to prevent attempts by third party payers to institute time limits on visits and stresses the importance of ensuring that physicians maintain their autonomy as it pertains to determining the length of visits. Finally, in order for physicians to be able to have the autonomy and voice in visit length desired, it is essential that they are involved in the governance and leadership of their employers. Therefore, the Council recommends reaffirmation of Policy D-225.977, which supports employed physician autonomy in clinical decision-making and self-governance.

It is clear that physicians who are practicing in settings with more intense time pressures are more likely to experience burnout, dissatisfaction, and stress, along with burgeoning desire to leave practice. While it is important to ensure that physicians are able to practice in a setting that is conducive to their staying in practice, it is particularly important in the face of a physician shortage. Therefore, the Council recommends reaffirmation of Policy H-405.957, which supports the implementation of programs that are aimed to identify and manage stress and burnout in physicians and medical students.

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) support efforts to ensure that physicians are able to exercise autonomy in the length of patient care visits free from undue influence from outside entities such as, but not limited to, payers, administrators, and health care systems.

2. That our AMA support efforts to incorporate patient complexities and social determinants of health in calculating appropriate amounts of expected patient care time.
3. That our AMA reaffirm Policy H-70.976 which monitors and seeks to prevent attempts by third-party payers to institute policies that impose time and diagnosis limits.
4. That our AMA reaffirm Policy D-225.977 that details support for employed physician involvement in self-governance and leadership.
5. That our AMA reaffirm Policy H-405.957 that describes AMA efforts to study, promote, and educate on physician well-being and to prevent physician burnout.
6. Rescind Policy D-450.951, as having been completed with this report.

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Council on Medical Service Report 3-I-24
Time-Limited Patient Care
Policy Appendix

Corporate Investors H-160.891

1. Our American Medical Association (AMA) encourages physicians who are contemplating corporate investor partnerships to consider the following guidelines:
    a. Physicians should consider how the practice's current mission, vision, and long-term goals align with those of the corporate investor.
    b. Due diligence should be conducted that includes, at minimum, review of the corporate investor's business model, strategic plan, leadership and governance, and culture.
    c. External legal, accounting and/or business counsels should be obtained to advise during the exploration and negotiation of corporate investor transactions.
    d. Retaining negotiators to advocate for best interests of the practice and its employees should be considered.
    e. Physicians should consider whether and how corporate investor partnerships may require physicians to cede varying degrees of control over practice decision-making and day-to-day management.
    f. Physicians should consider the potential impact of corporate investor partnerships on physician and practice employee satisfaction and future physician recruitment.
    g. Physicians should have a clear understanding of compensation agreements, mechanisms for conflict resolution, processes for exiting corporate investor partnerships, and application of restrictive covenants.
    h. Physicians should consider corporate investor processes for medical staff representation on the board of directors and medical staff leadership selection.
    i. Physicians should retain responsibility for clinical governance, patient welfare and outcomes, physician clinical autonomy, and physician due process under corporate investor partnerships.
    j. Each individual physician should have the ultimate decision for medical judgment in patient care and medical care processes, including supervision of non- physician practitioners.
    k. Physicians should retain primary and final responsibility for structured medical education inclusive of undergraduate medical education including the structure of the program, program curriculum, selection of faculty and trainees, as well as education and disciplinary issues related to these programs.
2. Our AMA supports improved transparency regarding corporate investment in physician practices and subsequent changes in health care prices.
3. Our AMA encourages national medical specialty societies to research and develop tools and resources on the impact of corporate investor partnerships on patients and the physicians in practicing in that specialty.
4. Our AMA supports consideration of options for gathering information on the impact of private equity and corporate investors on the practice of medicine. (CMS Rep. 11, A-19; Appended: CMS Rep. 2, I-22; Reaffirmed: BOT Rep. 14, A-23)

Limitation of Use of Time Component of Current Procedural Terminology (CPT-4) Coding H-70.976

Our AMA (1) adopts as policy that the time element in the new Evaluation and Management codes in the CPT-4 manual may be used to assist physicians and their staffs in determining appropriate levels of coding;
(2) opposes the use of the time elements to (a) judge how many of any given type of visit may be performed in any one hour; and (b) deny or downgrade services submitted based on a cumulative time;
(3) adopts as policy that there shall be no list of diagnoses used by third party payers to compare against the Evaluation and Management codes in such a fashion as to deny, downgrade, or in any other way seek to limit the submission of any CPT-4 code visit;
(4) will monitor attempts by the third party payers to institute such time limits and diagnosis limits; and
(5) will work with third party payers to prevent them from attempting to adopt and institute policies that would impose such time and diagnosis criteria. (Res. 823, A-92; Reaffirmation I-00; Reaffirmed: CMS Rep. 6, A-1; 0Reaffirmed: CMS Rep. 01, A-20)

Physician Burnout D-405.972

Our AMA will work with: (1) Centers for Medicare and Medicaid Services (CMS), The Joint Commission, and other accrediting bodies and interested stakeholders to add an institutional focus on physician wellbeing as an accreditation standard for hospitals, focusing on system-wide interventions that do not add additional burden to physicians; and (2) hospitals and other stakeholders to determine areas of focus on physician wellbeing, to include the removal of intrusive questions regarding physician physical or mental health or related treatments on initial or renewal hospital credentialing applications. (Res. 723, A-22; Reaffirmation I-22)

Programs on Managing Physician Stress and Burnout H-405.957

1. Our American Medical Association supports existing programs to assist physicians in early identification and management of stress and the programs supported by the AMA to assist physicians in early identification and management of stress will concentrate on the physical, emotional and psychological aspects of responding to and handling stress in physicians' professional and personal lives, and when to seek professional assistance for stress-related difficulties.
2. Our AMA will review relevant modules of the STEPs Forward Program and also identify validated student-focused, high quality resources for professional well-being, and will encourage the Medical Student Section and Academic Physicians Section to promote these resources to medical students. (Res. 15, A-15; Appended: Res. 608, A-16; Reaffirmed: BOT Rep. 15, A-19)

Physician and Medical Student Burnout D-310.968

1. Our AMA recognizes that burnout, defined as emotional exhaustion, depersonalization, and a reduced sense of personal accomplishment or effectiveness, is a problem among residents, fellows, and medical students.
2. Our AMA will work with other interested groups to regularly inform the appropriate designated institutional officials, program directors, resident physicians, and attending faculty about resident, fellow, and medical student burnout (including recognition, treatment, and prevention of burnout) through appropriate media outlets.
3. Our AMA will encourage partnerships and collaborations with accrediting bodies (e.g., the Accreditation Council for Graduate Medical Education and the Liaison Committee on Medical Education) and other major medical organizations to address the recognition, treatment, and prevention of burnout among residents, fellows, and medical students and faculty.
4. Our AMA will encourage further studies and disseminate the results of studies on physician and medical student burnout to the medical education and physician community.
5. Our AMA will continue to monitor this issue and track its progress, including publication of peer-reviewed research and changes in accreditation requirements.
6. Our AMA encourages the utilization of mindfulness education as an effective intervention to address the problem of medical student and physician burnout.
7. Our AMA will encourage medical staffs and/or organizational leadership to anonymously survey physicians to identify local factors that may lead to physician demoralization.
8. Our AMA will continue to offer burnout assessment resources and develop guidance to help organizations and medical staffs implement organizational strategies that will help reduce the sources of physician demoralization and promote overall medical staff well-being.
9. Our AMA will continue to: (a) address the institutional causes of physician demoralization and burnout, such as the burden of documentation requirements, inefficient work flows and regulatory oversight; and (b) develop and promote mechanisms by which physicians in all practices settings can reduce the risk and effects of demoralization and burnout, including implementing targeted practice transformation interventions, validated assessment tools and promoting a culture of well-being. (CME Rep. 8, A-07; Modified: Res. 919, I-11; Modified: BOT Rep. 15, A-19; Reaffirmation: A-22)

Factors Causing Burnout H-405.948

Our American Medical Association recognizes that medical students, resident physicians, and fellows face unique challenges that contribute to burnout during medical school and residency training, such as debt burden, inequitable compensation, discrimination, limited organizational or institutional support, stress, depression, suicide, childcare needs, mistreatment, long work and study hours, among others, and that such factors be included as metrics when measuring physician well-being, particularly for this population of physicians. (Res. 208, I-22)

Physician Independence and Self-Governance D-225.977
Our American Medical Association will continue to assess the needs of employed physicians, ensuring autonomy in clinical decision-making and self-governance.
Our AMA will promote physician collaboration, teamwork, partnership, and leadership in emerging health care organizational structures, including but not limited to hospitals, health care systems, medical groups, insurance company networks and accountable care organizations, in order to assure and be accountable for the delivery of quality health care. (Res. 801, I-11; Modified: BOT Rep. 6, I-12; Reaffirmed: CCB/CLRPD Rep. 1, A-22)

Managed Care Education H-285.969
The AMA will continue to emphasize professionalism, patient and physician autonomy, patient and physician rights, and practical assistance to physicians as key principles to guide AMA advocacy efforts related to managed care. (Sub. Res. 707, A-95; Reaffirmed: CMS Rep. 7, A-05; Reaffirmed: CMS Rep. 1, A-15)

4. BIOSIMILAR COVERAGE STRUCTURES

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION: RECOMMENDATIONS ADOTPED AS FOLLOWS
REMAINDER OF THE REPORT FILED
See Policies D-125.989, H-100.940, H-110.987, H-110.997 and H-125.972

At the June 2024 Annual Meeting, the House of Delegates (HOD) adopted amended Resolution 207-A-24 which encourages the Federal Trade Commission (FTC) and Department of Justice (DOJ) Antitrust Division to closely scrutinize long-term exclusive contracts signed between biologics originators and pharmacy benefit manages (PBMs) to ensure they do not impede biosimilar development and uptake (Policy H-125.973). The HOD also referred a proposed new resolved clause to Resolution 207-A-24, which was introduced by the Medical Student Section and asked the American Medical Association (AMA) to "support coverage structures that increase use of lower cost biosimilars when clinically appropriate, share savings between patients and payers, and reduce patient costs."

This report provides an overview of biosimilars, the current state of coverage, and related incentives to increase their use. Additionally, this report presents policy recommendations consistent with intent of the referred new resolved clause to Resolution 207-A-24.

BACKGROUND

A biosimilar drug is a type of biologic, or drug that is produced by living organisms, which is very similar in both structure and function to a Food and Drug Administration (FDA) approved branded biologic, or reference medication. Biosimilars may not have the same chemical compound as the reference medication but must have the same efficacy and chemical structure to act on the body (detailed definitions can be found in Appendix A).1 They are often compared to generic medications; however, they are slightly different. While generic medications are identical to the name brand medication, biosimilars have the same performance as the reference biologic, but there are slight chemical differences in the makeup of the medications.[1] For a more in-depth discussion as to the chemical and molecular makeup of biologic medications, how they differ from the reference medication, and interchangeability please see Council on Science & Public Health Report 5-A-24, *Biosimilar/Interchangeable Terminology*.

While biosimilars have been on the European market since 2006, the first biosimilar was approved by the FDA for use in the United States (U.S.) in 2015.2 Since then, the U.S. market has seen steady, if rather slow, growth of biosimilars.3,4,5 Between 2015 and 2020, only nine biosimilar medications entered the U.S. market. However, in recent years there has been significant growth in this market; as of August 2024, there are 59 FDA approved biosimilars in the U.S. market.6 In 2010, via a portion of the Affordable Care Act (ACA), the Biologics Price Competition and Innovation Act, Congress passed an abbreviated pathway to licensure in order to encourage increases in biosimilar approval in the U.S..[4,5,7] This abbreviated pathway from the ACA made it possible for

biosimilars to be approved in a more efficient manner. Congressional support for biosimilars was primarily based on the potential for financial savings that these medications have for both payers and patients.[3,4,]8

Biosimilars are often thought of as preferable to their equivalent reference medication due to the fact that they are typically less expensive. Cost savings have been seen in both the European Union and the United Kingdom National Health System, which have each saved millions annually by switching to biosimilar medications.[5] Estimates indicate that the use of biosimilar medications could result in a 15-35 percent overall savings in the U.S. market.[5,7,8,]9 This is especially important as biologic medications account for just over 40 percent, or about $211 billion, of all annual drug spending in the U.S..[9,]10 Some research has indicated that an increase in the use of biosimilars could save the U.S. health care system nearly $54 billion over 10 years.[4,5] While there have been actual savings in the U.S. due to the use of biosimilars, they have only amounted to $12.6 billion, or five percent of a projected $54 billion savings. Additionally, research indicates that savings to patient out-of-pocket cost is, if present at all, only marginal and very dependent on medication type.[7,8]

While it is possible that savings have not been realized due to slow introduction of biosimilars to the U.S. market, it is also possible that payment structures often do not incentivize the switch to biosimilar medications.[7] Recent research finds that there may be several factors affecting the likelihood of biosimilar initiation, including type of insurance coverage and patient age.11 Medicare Advantage beneficiaries were the most likely to initiate, accounting for 74 percent of all biosimilar initiation. Pediatric patients were the least likely to initiate, likely due to complications of approvals for use in children. Overall, the study found that biosimilar initiation is growing, with 27 percent of patients initiating biosimilars in 2022, up from one percent in 2013.[11]

Despite the initial Congressional support and potential for cost savings, biosimilar use has been limited in the U.S. since their initial approval. A leading factor in the slow uptake of biosimilars is centered around patents. Specifically, manufacturers of the reference medication are able to use strategies, like a minor formula or name change, to ensure that patents last longer in order to delay the entry of biosimilars to the market.[7,8] Additionally, payment structures have historically not incentivized the use of biosimilars over reference medications. A full discussion of the impact of coverage structures can be found in a later section of this report. Furthermore, there has been a significant learning curve for patients and physicians as to the potential advantages of choosing a biosimilar medication over a reference medication.

While federal legislation related to biosimilars has been sluggish,[4] the vast majority of states have laws allowing, or in some cases requiring, the substitution of biosimilars.12 All but four states, Alabama, Indiana, South Carolina, and Washington, have laws that allow for the automatic substitution of biosimilars for a prescribed reference medication by a pharmacist. In nine states, substitution is only permitted if the cost of the biosimilar is lower than the reference medication. Additionally, nearly all states with these laws require that both the patient and physician be notified regarding this change. Importantly, in every state, physicians and other prescribers are able to prevent automatic substitution by indicating that the prescription be "dispensed as written."[12] Regardless of law, it is important to note that physicians are generally wary of pharmacist-led drug substitutions, and the AMA has advocated widely on this issue and a discussion of efforts can be found in the policy and advocacy section of this report.

BIOSIMILAR COVERAGE

Historically, public and private payers in the U.S. have not incentivized the use of biosimilar medications and, in some cases, actually incentivized the use of reference biologic medications.[4,7,8,9,]13 While rebate information is not publicly disclosed, experts hypothesize that due to the higher list price of biologic reference medications, payers are able to negotiate greater rebates, making the reference medication more financially lucrative for the payer. As a result, payers may not include biosimilar medications on preferred formulary tiers or may deny coverage altogether.[12] Research has indicated that among 17 major private insurance plans, less than half had at least one biosimilar placed on a "preferred" formulary tier and only two plans placed at least half of biosimilar medications on the "preferred" tier.[7] Additionally, research indicates that private payers are either excluding or imposing serious restrictions on biosimilar medication coverage nearly 20 percent of the time. Coverage is most likely to be given in cases of cancer treatment and least likely in pediatric patients.[10] Recently, a few major plans have started to shift to cover biosimilars instead of the reference biologic. Interestingly, plans managed by the three largest PBMs were less likely to impose coverage restrictions on biosimilar medications. It is thought that this is a result of these PBMs leveraging their significant market power to negotiate for more advantageous rebates on biosimilars.[10,]14

In addition to the recent shift towards private payers covering biosimilars, federal legislation has encouraged the usage of biosimilars. The Bipartisan Budget Act of 2018 implemented Medicare formulary changes that provided discounts for biosimilars and led to 23 percent higher coverage of these medications.[5,9] The Inflation Reduction Act of 2022 (IRA) is likely to begin incentivizing biosimilar use in the Medicare program starting in 2025. The IRA has, among other things, a focus on lowering the cost of prescription medication for Medicare beneficiaries and to reduce the federal government's drug spending.15,16 Historically, Medicare Part D, the portion of Medicare that covers prescription medications, has favored reference biologics over biosimilars. Biosimilars are covered at 80 percent, but only when the patient reaches the "catastrophic coverage" phase, meaning that the patient's out-pf-pocket spending has exceeded $8,000. Prior to patients reaching this phase, plans are formulated in a manner where the reference medication is covered more advantageously.[15]

The IRA has two portions that are expected to significantly alter this and lead to greater coverage of biosimilars before patients reach the "catastrophic coverage" phase. First, the IRA implements federally-mandated discounts for certain branded drugs. This is likely to lessen the power of high list prices yielding more lucrative rebates for payers, thereby removing a major incentive to choose reference biologics over biosimilars. Second, the IRA altered Medicare's catastrophic coverage by eliminating the beneficiary coinsurance requirement. Specifically, the IRA capped out-of-pocket costs at $3,250 and added a hard cap on out-of-pocket spending of $2,000. This is indexed in future years to the rate of increase in per capita Part D costs. It is anticipated that this removal of the catastrophic coverage gap will motivate coverage decisions to favor biosimilars over the reference biologic.[15,16] Additionally, the IRA implemented guidelines to ensure that physicians are not incentivized to prescribe higher cost medications due to greater reimbursement based on the higher sticker price. Specifically, starting in October 2022 the IRA implemented an add-on payment rate for biosimilars if the average sale price of that medication is lower than the reference biologic. This is intended to not only incentivize the use of lower-cost biosimilars but also mitigate issues around physician incentivization based in greater reimbursement for higher-cost biologics.[15]

BIOSIMILAR INCENTIVES

Trends in both public and private payers indicate that biosimilars will not only be covered at a greater rate, but plans may actually be transitioning to incentivizing their use.[14,17] Additionally, across all payer types, biosimilar medications are moving towards self-administration, eliminating the need for a medical professional to administer the medication. This is significant as the administration change may lead to more biologic, both reference and biosimilar, medications to be covered under plans' pharmacy benefits. Coverage under the pharmacy benefit could in turn allow for more efficient switches to biosimilar medications.[14]

In addition to medication administration changes, other incentives are being implemented to ensure greater use of biosimilar medications when clinically appropriate, such as the movement of financial incentives to biosimilars in lieu of reference biologics. Historically, the rebates tied to reference biologics have made them the more financially lucrative choice for payers. However, due in part to a 2022 Executive Order from the Biden Administration to the FDA, the FTC, and the Centers for Medicare & Medicaid Services, financial incentives for payers have started to shift towards biosimilar medications.[10] In turn, some plans are utilizing financial incentives for patients to encourage switching to biosimilars. Plans have provided patients with a monetary reward for switching from a reference biologic to a biosimilar.[14] Additionally, initial research indicates that payers are placing biosimilars on formularies or on more advantageous formulary tiers at a greater rate in recent years.[14]

It remains to be seen if payers' biosimilar financial savings will be passed on to patients in the long-term. However, it does seem that the financial incentives are initially leading to greater coverage of biosimilar medications. If the switch to biosimilar medications is to be successful, it is vital that physicians and patients are adequately educated and in control of the switch. With time, physicians have become increasingly well-educated on biosimilars and their potential advantages, allowing some to become more comfortable; however, others continue to express concern.18,19 It is important to note that there are still significant legitimate concerns from physicians related to switching to biosimilars. For example, studies have found that as many as 65 percent of physicians indicated concerns with switching a patient from a reference biologic to a biosimilar medication. Physicians listed a wide range of reasons for concern related to the safety, efficacy, and immunogenicity of the biosimilar.[14]

It is also important that patients are adequately educated and supported in the use of biosimilars. Research has demonstrated that patients, like physicians, have a diverse set of opinions on the use of biosimilars.[19] While financial incentives or savings can be a powerful tool to increase interest in a biosimilar medication, some patients cite other

advantages of a reference biologic, driving resistance to switching to a biosimilar. Specifically, services from reference biologic medication manufacturers like copay support, on-call support/transport services, and educational or administration materials/devices are often powerful in maintaining patient preference for the reference biologic over the biosimilar.[4,14] Additionally, patients often echo physician concerns related to the safety, efficacy, and immunogenicity of biosimilar medications.[18,19] While some of these concerns can be mitigated by physician/patient education as to the benefits of biosimilars, it is important to ensure that any switch to a biosimilar medication is done in agreement from both the physician and patient.

Finally, two strategies seem to be particularly salient to incentivize the use of biosimilars. First, ensuring that patient cost-sharing or out-of-pocket costs are reduced. In many European countries, patient cost-sharing strategies have been utilized to incentivize the use of biosimilars. Specifically, countries have adopted policies that dictate more expensive medications have a higher co-pay and cheaper medications have a lower co-pay. In some cases, such as in Germany, the lower cost biosimilar has a copay as low as zero dollars, resulting in significant patient incentive to use that medication. Initial implementation of these plans seems to be resulting in higher uptake of the biosimilars with higher patient cost-sharing.[20] Second, allowing for cost-sharing to be shared between the physician and the patient. Shared savings-type programs have been successfully implemented in international settings and, more recently, in the Medicare program.20·21 In France and Germany, shared savings programs have been implemented with the intent of increasing biosimilar use. These programs are based on agreements between payers and hospitals/physicians regarding the cost savings of specific biosimilars. Initial research has shown that these programs have been successful in increasing the rate of biosimilar uptake in both countries.[19]

AMA POLICY & ADVOCACY

The AMA has a strong body of policy meant to ensure that prescription medications are affordable and that physicians are educated about and able to prescribe biosimilars. Policy H-110.997 supports physician involvement in prescription medication pricing and ensuring that physicians are able to prescribe the medication that is best for the patient. Policy H-110.987 supports advocacy with federal legislators and regulators to reduce anticompetitive behaviors, like patent manipulation, in drug manufacturing and outlines the importance of physician support in lowering pharmaceutical costs. Policy H-110.990 outlines efforts to ensure that cost-sharing and out-of-pocket costs for prescription drugs are fair and patient-friendly.

In addition to policy designed to ensure that prescription drugs are affordable and accessible to patients and that physicians can prescribe what is most clinically appropriate, the AMA has policy supporting the use of biosimilar medications. Policy D-125.989 supports physician autonomy in determining if a biosimilar or biologic product is dispensed to a patient and ensuring that switches from biologics to biosimilars are not done without notification and authorization of the prescribing physician. Policy H-125.972 outlines AMA efforts to support physician education on biosimilars, their FDA approval process, and surveillance requirements. Policy H-125.973 encourages the FTC and DOJ Antitrust Division to closely scrutinize long-term exclusive contracts signed between biologic originators and PBMs to ensure they do not impede biosimilar development and update.

In addition, the AMA has engaged in extensive state level advocacy regarding substitution of interchangeable biosimilar biologic products since 2012. The AMA has worked with dozens of medical societies to support state amendments to pharmacy practice acts to align with new federal definitions. For example, AMA advocated in support of new laws in Indiana, Washington and Mississippi. Based on the concern many physicians express related to pharmacist-led substitution, these laws support the authority of physicians to limit substitution of biologic products. The AMA has rather extensive policy that both works to maintain the proper scope of pharmacist practice and allow physicians to limit or prevent substitution. Specifically, Policies H-125.995 and D-35.987 outline AMA opposition to pharmacist-led substitution without express permission from the physician. Additionally, Policies H-125.991, H-120.918, and D-120.922 all detail efforts to ensure that physicians have the ability to dictate that a prescription should be dispensed as written.

DISCUSSION

Since their approval in the U.S., the initial uptake of biosimilar medications has been slow, but recent years have demonstrated a quicker uptick in their market availability. Public and private payers are continuing to make changes that will likely incentivize and, in turn, increase the prevalence and use of biosimilar medications in the U.S. IRA-derived revisions to the Medicare Part D benefit will be implemented in 2025, and it is likely that these changes will

further encourage the coverage of biosimilars, initially by public payers and, with time, by private payers as well. Additionally, recent changes by large insurers and PBMs have signaled that these players are moving towards not only covering biosimilars at a greater rate but incentivizing their use via financial rewards. In order to ensure that these financial rewards are passed on to patients so that biosimilar medications are affordable and accessible, the Council recommends the reaffirmation of Policies H-110.987 and H-110.997, which both outline advocacy efforts to ensure that prescription medications are affordable and accessible to patients.

If biosimilars are to be successfully incentivized, it is important that it be done holistically and inclusively for all parties involved, and not just centered around financial incentives to payers, and that no physician is forced to prescribe a biosimilar. In some cases, patients and/or physicians may not be comfortable with prescribing a biosimilar over the reference medication. This could be for a number of reasons, including concerns about the safety, efficacy, and/or immunogenicity of the biosimilar. Therefore, the Council recommends the reaffirmation of Policy H-125.989 which ensures that physicians are able to switch patients to biosimilars if they wish, but no substitutions can be made without the notification and approval of the prescribing physician. To ensure that physicians are comfortable and confident in prescribing and discussing biosimilars, the Council recommends the reaffirmation of Policy H-125.972 which outlines support for physician education on the topic of biosimilars.

Finally, in order to further encourage the use of biosimilars, the Council recommends the adoption of two new policies. First, to lower patient out-of-pocket costs, when deemed appropriate by the physician and amenable to the patient, the Council recommends the adoption of new policy to support the development and implementation of incentivization strategies to increase the use of biosimilar medications, when agreed upon by the patient and physician. Second, to ensure that patients are knowledgeable and comfortable with switching from a reference medication to a biosimilar medication, the Council recommends the adoption of new policy to support patient education on the topic of biosimilars by appropriate organizations.

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):
    a. support the development and implementation of strategies to incentivize the use of lower cost biosimilars when safe, fiscally prudent for the patient, and not financially disadvantageous to the clinical practice, clinically appropriate, and agreed upon as the best course of treatment by the patient and physician, and
    b. advocate to eliminate acquisition cost and reimbursement disparities for in-office biosimilar treatment across diverse treatment locations.
2. That our AMA support patient education regarding biosimilars and their safety and efficacy.
3. That our AMA reaffirm Policy H-110.987, which works to ensure that prescription medications are affordable and accessible to patients.
4. That our AMA reaffirm Policy H-110.997 which supports the freedom of physicians in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in making these choices.
5. That our AMA reaffirm Policy D-125.989, which outlines efforts to ensure that physicians are able to transition patient to biosimilar medications with coverage from payers.
6. That our AMA reaffirm Policy H-125.972 which details efforts to encourage physician education related biosimilars.

APPENDIX A
Definitions of key terms

Biologic drug (or large molecule drugs): a classification of drugs which are produced by living organisms (such as human or animal cells, yeast, or bacteria), rather than by chemical synthesis. As such, this class of drug tends to replicate or mimic common biologic entities. For example, antibody- or protein-based drugs are common examples of biologic drugs.

Small molecule drug: A classification of drugs based on the number of atoms (typically <100) in their structure. Small molecule drugs are generally prepared using chemical synthesis techniques. Small molecule drugs are

estimated to represent over 90 percent of all pharmaceuticals used in the clinic today. Typically, small molecule drugs function by binding to a biological entity (protein, receptor, etc.) and altering its function.

Generic drug: A drug produced by a second manufacturer after the patent or other market protections have expired, allowing for manufacturers to be able to produce their own products with the same chemical substance as a branded drug. The term generic drug only applies to small molecule drugs, with few exceptions.

Biosimilar: A biologic drug that has a very similar structure and function to a branded biologic drug after its patent or market protections have expired. Unlike generic drugs, biosimilars are not required to be the same chemical compound, but they are required to have the same chemical structure to act on the body and efficacy.

Interchangeable: An additional designation provided for biosimilar drugs by the FDA. This designation is not required for market approval and indicates that a biosimilar has successfully demonstrated no changes in efficacy or immunogenicity when the biosimilar is substituted for the reference product after a patient has already initiated treatment with the reference product. This designation has implications for reimbursement, and state regulations around pharmacist practice.

Note: these definitions were originally outlined in the Council on Science & Public Health Report 5-A-24, Biosimilar/Interchangeable Terminology. A more in-depth discussion as to the scientific details of these definitions, and biosimilars in general, can be found in the aforementioned CSAPH report.

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Biosimilar Coverage Structures
Policy Appendix

Cost of Prescription Drugs H-110.997
Our American Medical Association (AMA):
(1) supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied: (a) physicians must have significant input into the development and maintenance of such programs; (b) such programs must encourage optimum prescribing practices and quality of care; (c) all patients must have access to all prescription drugs necessary to treat their illnesses; (d) physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and (e) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs;
(2) reaffirms the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in making these choices;
(3) encourages physicians to stay informed about the availability and therapeutic efficacy of generic drugs and will assist physicians in this regard by regularly publishing a summary list of the patient expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products;
(4) encourages expanded third party coverage of prescription pharmaceuticals as cost effective and necessary medical therapies;
(5) will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the AMA House of Delegates informed about the findings of these studies;
(6) encourages physicians to consider prescribing the least expensive drug product (brand name or FDA A-rated generic); and
(7) encourages all physicians to become familiar with the price in their community of the medications they prescribe and to consider this along with the therapeutic benefits of the medications they select for their patients.
(BOT Rep. O, A-90; Sub. Res. 126 and Sub. Res. 503, A-95; Reaffirmed: Res. 502, A-98; Reaffirmed: Res. 520, A-99; Reaffirmed: CMS Rep. 9, I-99; Reaffirmed: CMS Rep.3, I-00; Reaffirmed: Res. 707, I-02; Reaffirmation A-04; Reaffirmed: CMS Rep. 3, I-04; Reaffirmation A-06; Reaffirmed in lieu of Res. 814, I-09; Reaffirmed in lieu of Res. 201, I-11; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: BOT Rep. 14, A-18)

Pharmaceutical Costs 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 drugv 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 percent 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 percent or more each year or per course of treatment.
11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
14. Our AMA supports legislation that limits Medicare annual drug price increases to the rate of inflation.

(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; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Appended: BOT Rep. 14, A-19; Reaffirmed: Res. 105, A-19; Appended: Res. 113, I-21; Reaffirmed in lieu of: Res. 810, I-22; Reaffirmed: Res. 801, I-23; Reaffirmed: Res. 801, I-23)

Cost Sharing Arrangements for Prescription Drugs H-110.990

Our AMA:

1. believes that cost-sharing arrangements for prescription drugs should be designed to encourage the judicious use of health care resources, rather than simply shifting costs to patients;
2. believes that cost-sharing requirements should be based on considerations such as: unit cost of medication; availability of therapeutic alternatives; medical condition being treated; personal income; and other factors known to affect patient compliance and health outcomes;
3. supports the development and use of tools and technology that enable physicians and patients to determine the actual price and patient-specific out-of-pocket costs of individual prescription drugs, taking into account insurance status or payer type, prior to making prescribing decisions, so that physicians and patients can work together to determine the most efficient and effective treatment for the patient's medical condition;
4. supports public and private prescription drug plans in offering patient-friendly tools and technology that allow patients to directly and securely access their individualized prescription benefit and prescription drug cost information; and
5. believes payers should not establish a higher cost-sharing requirement exclusively for prescription drugs approved for coverage under a medical exceptions process.

(CMS Rep. 1, I-07; Reaffirmation A-08; Reaffirmed: CMS Rep. 1, I-12; Reaffirmed in lieu of Res. 105, A-13; Reaffirmed in lieu of: Res. 205, A-17; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: CMS Rep. 07, A-18; Appended: CMS Rep. 2, I-21; Reaffirmed: Res. 113, A-23Appended: CMS Rep. 01, A-23)

Substitution of Biosimilar Medicines and Related Medical Products D-125.989

Our AMA urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena: (1) preserve physician autonomy to designate which biologic or biosimilar product is dispensed to their patients; (2) allow substitution when physicians expressly authorize substitution of a product; (3) in the absence of express physician authorization to the contrary, allow substitution of the biologic or biosimilar product when (a) the biologic product is highly similar to the reference product, notwithstanding minor differences in clinically inactive components; and (b) there are no data indicating clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product; and (c) the prescribing physician has been adequately notified by the pharmacist.

(Res. 918, I-08; Modified: CSAPH Rep. 1, I-11; Modified: CSAPH Rep. 4, A-14; Modified; CSAPH Rep. 5, A-24)

Biosimilar/Interchangeable Terminology H-125.972

1. Our AMA encourages the FDA to continually collect data and critically evaluate biosimilar utilization including the appropriateness of the term "interchangeable" in regulatory activities.
2. Our AMA supports evidence-based physician education on the clinical equivalence of biosimilars, the FDA approval process, and post-market surveillance requirements. (CSAPH Rep. 5, A-24)

Therapeutic and Pharmaceutical Alternatives by Pharmacists H-125.995

The AMA opposes legislative attempts at any level of government that would permit pharmacists, when presented with a prescription for a drug product, to: (1) dispense instead a drug product that is administered by the same route and which contains the same pharmaceutical moiety and strength, but which differs in the salt or dosage form (pharmaceutical alternatives); and (2) dispense a drug product containing a different pharmaceutical moiety but which is of the same therapeutic and/or pharmacological class (therapeutic substitution). Our AMA will work with state medical associations to ensure that state pharmacy laws and medical practice acts are properly enforced so that treating physician's directions cannot be overruled or substituted without prior physician approval.
(Res. 89, I-85; Reaffirmed by Sub. Res. 501, A-95; Reaffirmed by CLRPD Rep. 2, I-95; Appended by Res. 501, A-98; Reaffirmed: CSAPH Rep. 2, A-08; Modified: CSAPH Rep. 01, A-18)

Evaluation of the Expanding Scope of Pharmacists' Practice, D-35.987

1. Our AMA will re-evaluate the expanding scope of practice of pharmacists in America and develop additional policy to address the proposed new services provided by pharmacists that may constitute the practice of Medicine.
2. Our AMA will continue to collect and disseminate state specific information in collaboration with state medical societies regarding the current scope of practice for pharmacists in each state; studying if and how each state is addressing these expansions of practice.
3. Our AMA will develop model state legislation to address the expansion of pharmacist scope of practice that is found to be inappropriate or constitutes the practice of medicine, including but not limited to the issue of interpretations or usage of independent practice arrangements without appropriate physician supervision and work with interested states and specialties to advance such legislation.
4. Our AMA opposes federal and state legislation allowing pharmacists to independently prescribe or dispense prescription medication without a valid order by, or under the supervision of, a licensed doctor of medicine, osteopathy, dentistry or podiatry.
5. Our AMA opposes federal and state legislation allowing pharmacists to dispense medication beyond the expiration of the original prescription.
6. Our AMA opposes the inclusion of Doctors of Pharmacy (PharmD) among those health professionals designated as a "Physician" by the Centers for Medicare & Medicaid Services.

(Res. 219, A-11; Appended: Res. 218, A-12; Reaffirmed: BOT Rep. 9, A-22)

Drug Formularies and Therapeutic Interchange H-125.991

It is the policy of the AMA:
(1) That the following terms be defined as indicated:
(a) Formulary: a compilation of drugs or drug products in a drug inventory list; open (unrestricted) formularies place no limits on which drugs are included whereas closed (restrictive) formularies allow only certain drugs on the list;
(b) Formulary system: a method whereby the medical staff of an institution, working through the pharmacy and therapeutics committee, evaluates, appraises, and selects from among the numerous available drug entities and drug products those that are considered most useful in patient care;
(c) Pharmacy & Therapeutics (P&T) Committee: an advisory committee of the medical staff that represents the official, organizational line of communication and liaison between the medical staff and the pharmacy department; its recommendations are subject to medical staff approval;
(d) Therapeutic alternates: drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class, and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses;
(e) Therapeutic interchange: authorized exchange of therapeutic alternates in accordance with previously established and approved written guidelines or protocols within a formulary system; and
(f) Therapeutic substitution: the act of dispensing a therapeutic alternate for the drug product prescribed without prior authorization of the prescriber.
(2) That our AMA reaffirms its opposition to therapeutic substitution (dispensing a therapeutic alternate without prior authorization) in any patient care setting.

(3) That drug formulary systems, including the practice of therapeutic interchange, are acceptable in inpatient hospital and other institutional settings that have an organized medical staff and a functioning Pharmacy and Therapeutics (P&T) Committee, provided they satisfy the following standards:

(a) The formulary system must:

(i) have the concurrence of the organized medical staff;

(ii) openly provide detailed methods and criteria for the selection and objective evaluation of all available pharmaceuticals;

(iii) have policies for the development, maintenance, approval and dissemination of the drug formulary and for continuous and comprehensive review of formulary drugs;

(iv) provide protocols for the procurement, storage, distribution, and safe use of formulary and non-formulary drug products;

(v) provide active surveillance mechanisms to regularly monitor both compliance with these standards and clinical outcomes where substitution has occurred, and to intercede where indicated;

(vi) have enough qualified medical staff, pharmacists, and other professionals to carry out these activities;

(vii)provide a mechanism to inform the prescriber in a timely manner of any substitutions, and that allows the prescriber to override the system when necessary for an individual patient without inappropriate administrative burden;

(viii) provide a mechanism to assure that patients/guardians are informed of any change from an existing outpatient prescription to a formulary substitute while hospitalized, and whether the prior medication or the substitute should be continued upon discharge from the hospital;

(ix) include policies that state that practitioners will not be penalized for prescribing non-formulary drug products that are medically necessary; and

(x) be in compliance with applicable state and federal statutes and/or state medical board requirements.

(b) The P&T Committee must:

(i) objectively evaluate the medical usefulness and cost of all available pharmaceuticals (reliance on practice guidelines developed by physician organizations is encouraged);

(ii) recommend for the formulary those drug products which are the most useful and cost-effective in patient care;

(iii) conduct drug utilization review (DUR) activities;

(iv) provide pharmaceutical information and education to the organization's (e.g., hospital) staff;

(v) analyze adverse results of drug therapy;

(vi) make recommendations to ensure safe drug use and storage; and

(vii) provide protocols for the timely procurement of non-formulary drug products when prescribed by a physician for the individualized care of a specific patient, when that decision is based on sound scientific evidence or expert medical judgment.

(c) The P&T Committee's recommendations must be approved by the medical staff;

(d) Within the drug formulary system, the P & T Committee shall recommend, and the medical staff must approve, all drugs that are subject to therapeutic interchange, as well as all processes or protocols for informing individual prescribing physicians; and

(e) The act of providing a therapeutic alternate that has not been recommended by the P&T Committee and approved by the medical staff is considered unauthorized therapeutic substitution and requires immediate prior consent by the prescriber; i.e., authorization for a new prescription.

(4) That drug formulary systems in any outpatient setting shall operate under a P&T Committee whose recommendations must have the approval of the medical staff or equivalent body, and must meet standards comparable to those listed above. In addition:

(a) That our AMA continues to insist that managed care and other health plans identify participating physicians as their “medical staff” and that they use such staff to oversee and approve plan formularies, as well as to oversee and participate on properly elected P&T Committees that develop and maintain plan formularies;

(b) That our AMA continues to insist that managed care and other health plans have well-defined processes for physicians to prescribe non-formulary drugs when medically indicated, that this process impose minimal administrative burdens, and that it include access to a formal appeals process for physicians and their patients; and

(c) That our AMA strongly recommends that the switching of therapeutic alternates in patients with chronic diseases who are stabilized on a drug therapy regimen be discouraged.

(5) That our AMA encourages mechanisms, such as incentive-based formularies with tiered co-pays, to allow greater choice and economic responsibility in drug selection, but urges managed care plans and other third party payers to not excessively shift costs to patients so they cannot afford necessary drug therapies.

(BOT Rep. 45, I-93; Reaffirmed by Sub. Res. 501, A-95; Appended: BOT Rep. 7, I-99; Modified: Sub. Res. 524 and Reaffirmed: Res. 123, A-00; Reaffirmed: Res. 515, I-00; Reaffirmed: CMS Rep. 8, A-02; Reaffirmed: Res. 533, A-03; Modified: CMS Rep. 6, A-03; Modified: CSA Rep. 2, A-04; Reaffirmation I-04; Reaffirmed in lieu of Res. 535, A-05; Reaffirmed: BOT Action in response to referred for decision Res. 503, A-05; Reaffirmed: CMS Rep. 2, I-05; Reaffirmation A-06; Reaffirmation A-08; Reaffirmed: CMS Rep. 2, A-10; Reaffirmed: CMS Rep. 01, A-20)

Prescription Drug Dispensing Policies H-120.918

1. Our American Medical Association supports the development and implementation of clear guidelines and mechanisms to indicate that the quantity of a prescription should be dispensed only as written using such language as “dispense quantity as written” or “no change in quantity.”
2. Our AMA supports the development, implementation and/or use of electronic or other means of communication to provide cost and coverage information of various prescribing quantities at the point of care allowing physicians to make the best decisions with their patients regarding prescribed medication quantities.

(CMS Rep. 05, A-23)

Transparency at the Pharmacy Counter D-120.922

Our American Medical Association advocates for legislation or regulation that mandates that pharmacies, whether physical or mail-order, must inform patients about their prescriptions, to include at a minimum:

1. The dosage and schedule of treatments as written by the prescriber.
2. Any restriction or alteration of the prescriber’s intent due to third party or pharmacy intervention, with the stated justification.
3. Details of other avenues to obtain the original prescription, including out of pocket options, with comparative costs.

(Res. 718, A-24)

Biosimilar Use Rates and Prevention of Pharmacy Benefit Manager Abuse, H-125.973

Our American Medical Association will encourage the Federal Trade Commission (FTC) and Department of Justice (DOJ) Antitrust Division to closely scrutinize long-term exclusive contracts signed between biologics originators and PBMs to ensure they do not impede biosimilar development and uptake.

(Res. 207, A-24)