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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES (A-19)

Report of Reference Committee A

John Montgomery, MD, Chair

Your Reference Committee recommends the following consent calendar for acceptance:

RECOMMENDED FOR ADOPTION

1. Council on Medical Service Report 2 - Covering the Uninsured under the AMA Proposal for Reform
   in lieu of
   Resolution 116 - Medicare for All
2. Council on Medical Service Report 3 - Medicare Coverage for Dental Services
3. Council on Medical Service Report 5 - The Impact of Pharmacy Benefit Managers on Patients and Physicians
4. Council on Medical Service Report 6 - Preventive Prostate Cancer Screening
5. Resolution 102 - Use of HSAs for Direct Primary Care

RECOMMENDED FOR ADOPTION AS AMENDED OR SUBSTITUTED

6. Council on Medical Service Report 4 - Reclassification of Complex Rehabilitation Technology
7. Resolution 105 - Payment for Brand Medications When the Generic Medication is Recalled
8. Resolution 107 - Investigate Medicare Part D – Insurance Company Upcharge
9. Resolution 113 - Ensuring Access to Statewide Commercial Health Plans
   Resolution 114 - Ensuring Access to Nationwide Commercial Health Plans
10. Resolution 115 - Safety of Drugs Approved by Other Countries
    Resolution 129 - The Benefits of Importation of International Pharmaceutical Medications
11. Resolution 117 - Support for Medicare Disability Coverage of Contraception for Non-Contraceptive Use
12. Resolution 119 - Returning Liquid Oxygen to Fee Schedule Payment
13. Resolution 122 - Reimbursement for Telemedicine Visits
14. Resolution 124 - Increased Affordability and Access to Hearing Aids and Related Care
    in lieu of
    Resolution 120 - Medicare Coverage of Hearing Aids
15. Resolution 126 - Ensuring Prescription Drug Price Transparency from Retail Pharmacies

RECOMMENDED FOR REFERRAL FOR DECISION

16. Resolution 131 - Update Practice Expense Component of Relative Value Units

RECOMMENDED FOR REAFFIRMATION IN LIEU OF

17. Resolution 101 - Health Hazards of High Deductible Insurance
    Resolution 125 - Mitigating the Negative Effects of High-Deductible Health Plans
18. Resolution 109 - Part A Medicare Payment to Physicians
19. Resolution 111 - Practice Overhead Expense and the Site-of-Service Differential
    Resolution 132 (Late Resolution 1003) – Site of Service Differential
20. Resolution 112 - Health Care Fee Transparency
21. Resolution 123 - Standardizing Coverage of Applied Behavioral Analysis Therapy for Persons with Autism Spectrum Disorder
22. Resolution 127 - Eliminating the CMS Observation Status

Existing policy was reaffirmed in lieu of the following resolutions via the Reaffirmation Consent Calendar:

- Resolution 103 - Health System Improvement Standards
- Resolution 104 - Adverse Impacts of Single Specialty Independent Practice Associations
- Resolution 106 - Raising Medicare Rates for Physicians
- Resolution 108 - Congressional Healthcare Proposals
- Resolution 110 - Establishing Fair Medicare Payer Rates
- Resolution 118 - Pharmaceutical Pricing Transparency
- Resolution 121 - Maintenance Hemodialysis for Undocumented Persons
- Resolution 128 - Elimination of CMS Hospital Readmission Penalties
- Resolution 130 - Notification of Generic Drug Manufacturing Changes

(1) COUNCIL ON MEDICAL SERVICE REPORT 2 - COVERING THE UNINSURED UNDER THE AMA PROPOSAL FOR REFORM
RESOLUTION 116 - MEDICARE FOR ALL

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the recommendations in Council on Medical Service Report 2 be adopted in lieu of Resolution 116 and the remainder of the report be filed.

HOD ACTION: The recommendations in Council on Medical Service Report 2 adopted in lieu of Resolution 116 and the remainder of the report filed.

Council on Medical Service Report 2 recommends that our AMA support eliminating the subsidy "cliff", thereby expanding eligibility for premium tax credits beyond 400 percent of the federal poverty level (FPL); support increasing the generosity of premium tax credits; support expanding eligibility for cost-sharing reductions; support increasing the size of cost-sharing reductions; and reaffirm Policies H-165.828, H-165.842, H-165.824, D-290.979, H-290.965, H-290.976, H-290.971, H-290.982, D-290.982 and D-165.942.

Resolution 116 asks that our AMA gather current, accurate data on the reimbursement from Medicare for private practice physicians, medical clinics, hospital outpatient services, hospitals including rural hospitals and critical access hospitals, and healthcare systems along with accurate data as to how the reimbursement compares to the cost for providing the medical care for these services; evaluate what would happen to the healthcare economics of the United States and the ability to continue outpatient medical practice if the current Medicare reimbursement, compared to the cost of providing that care, became the major financing resource for medical care and predict what effect this would have on the access to medical care in the U.S.; evaluate how the current differential payments in Medicare to various entities for the same service would change in a "Medicare for all" scenario; after analysis of the data, provide to the patients and physicians of our country the relevant questions that we can ask of political candidates advocating "Medicare for all"; and provide a better understanding of the impact of "Medicare for all" in terms of healthcare financing, workforce, ability to continue private practice medical care, incentives for physicians to join hospital systems, availability of care, and help understand how this might change the provision of healthcare in the United States.

Your Reference Committee heard predominantly supportive testimony on Council on Medical Service Report 2. In introducing the report, a member of the Council on Medical Service underscored that by putting forward strong recommendations to improve the Affordable Care Act (ACA), the Council report appropriately targets providing coverage to the uninsured population, as well as making coverage more affordable for millions of Americans. At the same time, the report recommendations recognize that almost 60 percent of nonelderly Americans (more than 156 million) are enrolled in employer-sponsored insurance, and are generally satisfied with their coverage.

Testimony on Resolution 116 was mixed. Notably, many speakers stressed that adopting Resolution 116 would have unintended consequences. Importantly, a member of the Council on Medical Service noted that Council on Medical Service Report 2 addressed the intent of Resolution 116, and should be adopted in lieu of the resolution. The President of the AMA urged support for Council on Medical Service Report 2. In her testimony, she noted that the recommendations of Council on Medical Service Report 2 build upon the AMA's extensive policy foundation—supporting individually owned health insurance with tax credits inversely related to income—that was established in 1998. She continued that the Council's recommendations respond to policy gaps to ensure that the AMA proposal for reform has the potential to cover millions more Americans. Important to those in our House who are disappointed that the Council on Medical Service did not recommend removing AMA's opposition to single payer proposals, she stressed that the AMA will be at the table as health reform proposals are introduced and debated—just as we were from when our "Voice for the Uninsured" campaign launched in 2007 up to the passage of the ACA.

A member of the Council on Legislation also testified in strong support of the report, noting that since the enactment of the ACA in 2010, the AMA has been highly engaged on the legislative, regulatory and judicial fronts regarding the law's implementation, guided by policy. Notably, the member of the Council on Legislation noted that the recommendations of CMS Report 2 to eliminate the "subsidy cliff", make premium tax credits more generous, and expand eligibility for and increase the size of cost-sharing reductions are in line with recent federal legislation that has been introduced to improve the ACA. The Council member stated that having policy specifically on point for these provisions would be incredibly meaningful to AMA advocacy efforts, and lead to millions more Americans to get covered. Finally, the member of the Council on Legislation stated that it looked forward to continuing to review legislation that is introduced, ranging from ACA improvement legislation to other bills that may not be in clear alignment with AMA policy. Importantly, it was stressed that having policy in opposition to single payer proposals would not prevent the Council on Legislation from evaluating proposals as they are introduced, that will vary greatly in substance and scope.

An amendment was offered for our AMA to support public choice options that would allow individuals and families a choice of publicly-financed or private insurance as long as payments to physicians are appropriate, sufficient, fair, and sustainable (not limited to Medicare rates) to ensure access to care. The amendment received strong support. A member of the Council on Medical Service welcomed study of the coverage options outlined in the amendment. Your Reference Committee agrees with need for study, and believes that the impacts of the options outlined in the amendment on coverage rates, affordability, health plan choice, the Medicare Trust Fund, and crowd-out from private to public coverage must be comprehensively analyzed before enacting any change to AMA policy. Accordingly, your Reference Committee is proposing such a study alongside Resolutions 113 and 114 (see item 9). Your Reference Committee also notes that our AMA already has policy addressing a public option. Policy H-165.838 states that insurance coverage options offered in a health insurance exchange be self-supporting; have uniform solvency requirements; not receive special advantages from government subsidies; include payment rates established through meaningful negotiations and contracts; not require provider participation; and not restrict enrollees' access to out-of-network physicians.

An amendment was also offered to remove AMA policy opposition to single-payer proposals – which is the focus of the referred resolution to which Council on Medical Service Report 2 responded. Your Reference Committee agrees with the Council on Medical Service that our AMA proposal for reform provides a strong policy foundation to use in evaluating health reform proposals as they get introduced in the coming years, regardless of whether they are tied to the ACA. Your Reference Committee heard testimony from members of the Board of Trustees and the Council on Legislation that even with policy opposition to single-payer proposals, our AMA will continue to thoughtfully engage in discussions of health reform proposals, which will vary greatly in their structure and scope.

Your Reference Committee thanks the Council on Medical Service for a comprehensive report. Your Reference Committee agrees that our AMA proposal for reform, including the report recommendations, outlines a strong strategy to cover the remaining uninsured, with specific, targeted policy proposals for the uninsured subpopulations. Importantly, your Reference Committee notes that the Council report recommendations promote physician practice viability by maintaining the variety in the potential payer mix for physician practices that is essential to cover practice expenses, as well as support payment and delivery reforms. As such, your Reference Committee recommends that the recommendations of Council on Medical Service Report 2 be adopted in lieu of Resolution 116, and the remainder of the report be filed.

(2) COUNCIL ON MEDICAL SERVICE REPORT 3 - MEDICARE COVERAGE FOR DENTAL SERVICES

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the recommendations in Council on Medical Service Report 3 be adopted and the remainder of the report be filed.

HOD ACTION: The recommendations in Council on Medical Service Report 3 adopted and the remainder of the report filed.

Council on Medical Service Report 3 recommends that our AMA reaffirm Policy D-160.925; support continued opportunities to work with the American Dental Association and other interested national organizations to improve access to dental care for Medicare beneficiaries; and support initiatives to expand health services research on the effectiveness of expanded dental coverage in improving health and preventing disease in the Medicare population, the optimal dental benefit plan designs to cost-effectively improve health and prevent disease in the Medicare population, and the impact of expanded dental coverage on health care costs and utilization.

Testimony on Council on Medical Service Report 3 was unanimously supportive. In introducing the report, a member of the Council on Medical Service underscored the fact that the ADA is currently engaged in their own study of a potential Medicare dental benefit so that they can make an informed recommendation for their profession. The Surgeon General testified supporting oral health and efforts to cover oral health care.

The Surgeon General explained that while he is not permitted to express an advocacy opinion on the matter, he applauded Council on Medical Service Report 3, and thanked the AMA for taking on this issue. Your Reference Committee believes that the recommendations of the report constitute important steps to improve dental care for Medicare beneficiaries, and recommends that the recommendations of Council on Medical Service Report 3 be adopted and the remainder of the report be filed.

(3) COUNCIL ON MEDICAL SERVICE REPORT 5 - THE IMPACT OF PHARMACY BENEFIT MANAGERS ON PATIENTS AND PHYSICIANS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the recommendations in Council on Medical Service Report 5 be adopted and the remainder of the report be filed.

HOD ACTION: The recommendations in Council on Medical Service Report 5 adopted and the remainder of the report filed.

Council on Medical Service Report 5 recommends that our AMA support the active regulation of pharmacy benefit managers (PBMs) under state departments of insurance; develop model state legislation addressing the state regulation of PBMs, which shall include provisions to maximize the number of PBMs under state regulatory oversight; support requiring the application of manufacturer rebates and pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to drug prices at the point-of-sale; support efforts to ensure that PBMs are subject to state and federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity; support outlined principles to improve transparency of PBM operations; encourage increased transparency in how DIR fees are determined and calculated; and reaffirm Policies H-125.979, H-320.939, H-285.965, D-330.910 and H-320.958.

Your Reference Committee heard highly supportive testimony on Council on Medical Service Report 5. In introducing the report, a member of the Council on Medical Service underscored that the recommendations of the report aim to increase transparency in PBM operations, while taking steps to increase state and federal regulation of PBMs in response to their role in managing drug benefits, which now resembles the typical role of insurers.

There was an amendment offered to advocate for stronger PBM reform at the federal level, including advocating for the elimination of rebates. A member of the Council on Medical Service raised concerns with the amendment, noting that the elimination of rebates would have unintended consequences, including higher premiums and cost-sharing. Further, a member of the Council on Legislation testified in support of Council on Medical Service Report 5, noting that the AMA has been highly engaged in advocating for PBM transparency and improved regulation of PBMs, from testifying before congressional committees, to submitting regulatory comments, to supporting

federal legislation, to leveraging model state legislation. For example, in his statement to the U.S. House of Representatives Energy and Commerce Committee Health Subcommittee for the hearing "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain," Dr. Jack Resneck, Chair, AMA Board of Trustees, testified in support of increased PBM transparency. In its statement for the record to the US House of Representatives Committee on Oversight and Reform on examining the actions of drug companies in raising prescription drug prices in January 2019, the AMA called for improved regulation and transparency of PBMs, priorities that were also echoed in the comments of the AMA submitted in response to American Patients First, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint) in July 2018.

Your Reference Committee believes that Council on Medical Service Report 5 is highly consistent with AMA advocacy efforts in support of increased transparency and regulation of PBMs. As such, your Reference Committee recommends that the recommendations of Council on Medical Service Report 5 be adopted and the remainder of the report be filed.

(4) COUNCIL ON MEDICAL SERVICE REPORT 6 - PREVENTIVE PROSTATE CANCER SCREENING

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the recommendations in Council on Medical Service Report 6 be adopted and the remainder of the report be filed.

HOD ACTION: The recommendations in Council on Medical Service Report 6 adopted and the remainder of the report filed.

Council on Medical Service Report 6 recommends that our AMA encourage public and private payers to ensure coverage for prostate cancer screening when the service is deemed appropriate following informed physician-patient shared decision-making; encourage national medical specialty societies to promote public education around the importance of informed physician-patient shared decision-making regarding medical services that are particularly sensitive to patient values and circumstances, such as prostate cancer screening; amend Policy D-450.957 to change the title to read, "Clinical Guidelines and Evidence Regarding Benefits of Prostate Cancer Screening and Other Preventive Services," and to add a new subsection, "(3) encouraging scientific research to address the evidence gaps highlighted by organizations making evidence-based recommendations about clinical preventive services"; and reaffirm Policies D-185.979, H-185.939, H-373.997, H-450.938, D-185.980 and H-425.997.

Testimony on Council on Medical Service Report 6 was unanimously and strongly supportive. In introducing the report, a member of the Council on Medical Service explained how medical services currently qualify for insurance coverage without patient cost-sharing and placed prostate cancer screening in the context of other cancer screening services that do not currently meet the evidentiary threshold required to

qualify for coverage without cost-sharing. In addition, the co-authors of the original resolution testified in strong support of Council on Medical Service Report 6 and thanked the Council for its report. Your Reference Committee believes that the recommendations of the report build off of existing policy guiding the coverage of preventive services, and recommends that the recommendations of Council on Medical Service Report 6 be adopted and the remainder of the report be filed.

(5) RESOLUTION 102 - USE OF HSAs FOR DIRECT PRIMARY CARE

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 102 be adopted.

HOD ACTION: Resolution 102 adopted.

Resolution 102 asks that our AMA adopt policy that the use of a health savings account (HSA) to access direct primary care providers and/or to receive care from a direct primary care medical home constitutes a bona fide medical expense, and that particular sections of the IRS code related to qualified medical expenses should be amended to recognize the use of HSA funds for direct primary care and direct primary care medical home models as a qualified medical expense; and seek federal legislation or regulation, as necessary, to amend appropriate sections of the IRS code to specify that direct primary care access or direct primary care medical homes are not health “plans” and that the use of HSA funds to pay for direct primary care provider services in such settings constitutes a qualified medical expense, enabling patients to HSAs to help pay for Direct Primary Care and to enter DPC periodic-fee agreements without IRS interference or penalty.

Your Reference Committee heard testimony supportive of the intent of Resolution 102. Your Reference Committee believes that Resolution 102 is consistent with existing policy and advocacy efforts, and as such recommends its adoption.

(6) COUNCIL ON MEDICAL SERVICE REPORT 4 - RECLASSIFICATION OF COMPLEX REHABILITATION TECHNOLOGY

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Recommendation 3 of Council on Medical Service Report 4 be amended by addition and deletion to read as follows:

3. That our AMA support, upon reclassification of CRT as a distinct category, the development by the Centers for Medicare & Medicaid Services, with the advice of physicians with appropriate training and expertise, of appropriate, simplified and streamlined ~~of additional~~ requirements ~~and/or regulations~~ specific to CRT that reduce the administrative burden on physicians.~~, beyond those that exist under the broad category of durable medical equipment.~~ (New HOD Policy)

RECOMMENDATION B

Madam Speaker, your Reference Committee recommends that the recommendations in Council on Medical Service Report 4 be adopted as amended and the remainder of the report be filed.

HOD ACTION: The recommendations in Council on Medical Service Report 4 adopted as amended and the remainder of the report filed.

Council on Medical Service Report 4 recommends that our AMA support the reclassification of complex rehabilitation technology (CRT) as a separate, distinct, and adequately funded payment category to improve access to the most appropriate and necessary equipment to allow individuals with significant disabilities and chronic medical conditions to increase their independence, reduce their overall health care expenses and appropriately manage their medical needs; support state medical association and national medical specialty society efforts to accomplish adequately funded reclassification of CRT; and support, upon reclassification of CRT as a distinct category, the development by the Centers for Medicare & Medicaid Services of additional requirements and/or regulations specific to CRT, beyond those that exist under the broad category of durable medical equipment.

Testimony on Council on Medical Service Report 4 was supportive. In introducing the report, a member of the Council on Medical Service noted that the Council specifically considered the potential impacts of reclassifying CRT as a separate and adequately funded payment category, and concluded that the reclassification was warranted. An amendment was offered to Recommendation 3 to strengthen and clarify the recommendation. A member of the Council on Medical Service testified in support of this amendment. Your Reference Committee accordingly recommends adoption of Council on Medical Service Report 4 as amended.

(7) RESOLUTION 105 - PAYMENT FOR BRAND MEDICATIONS WHEN THE GENERIC MEDICATION IS RECALLED

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the following alternate resolution be adopted in lieu of Resolution 105:

RESOLVED, That our AMA support health plans and pharmacy benefit managers providing a process for expedited formulary exceptions in the event of a recall of a generic medication, to ensure patient access to the brand medication or more affordable, alternative treatment options (New HOD Policy); and be further

RESOLVED, That our AMA reaffirm Policy H-110.987, which supports the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage or no available comparable generic drug (Reaffirm HOD Policy); and be further

RESOLVED, That our AMA reaffirm Policy H-100.956, which outlines policy priorities to respond to national drug shortages (Reaffirm HOD Policy).

HOD ACTION: Alternate resolution adopted in lieu of Resolution 105.

Resolution 105 asks that our AMA petition the Centers for Medicare and Medicaid Services as well as third party payers to allow reimbursement for brand medications at the lowest copayment tier so that patients can be effectively treated until the medication manufacturing crisis is resolved.

There was no testimony on Resolution 105. Your Reference Committee notes that in the case of a generic medication recall, the physician should be able to request an expedited formulary exception request for coverage of the brand if the patient needs to stay on the same drug product. Your Reference Committee also notes that recalls of generic medications can lead to other generic manufacturers of the same product to significantly increase their prices. As such, your Reference Committee has crafted an alternate resolution that addresses the intent of Resolution 105, and responds to the potential impacts of generic medication recalls.

H-100.956 National Drug Shortages
1. Our AMA considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients. 2. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can

mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion. 3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage. 4. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant. 5. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations on drug shortages, and report back at least annually to the House of Delegates on progress made in addressing drug shortages. 6. Our AMA urges the development of a comprehensive independent report on the root causes of drug shortages. Such an analysis should consider federal actions, the number of manufacturers, economic factors including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. In particular, further transparent analysis of economic drivers is warranted. The federal Centers for Medicare & Medicaid Services (CMS) should review and evaluate its 2003 Medicare reimbursement formula of average sales price plus 6% for unintended consequences including serving as a root cause of drug shortages. 7. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market due to compliance issues unless such removal is clearly required for significant and obvious safety reasons. 8. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history. 9. Our AMA will collaborate with medical specialty society partners and other stakeholders in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs. 10. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages. 11. Our AMA urges the FDA to require manufacturers to provide greater transparency regarding production locations of drugs and provide more detailed information regarding the causes and anticipated duration of drug shortages. 12. Our AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes. 13. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities. 14. Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan. (CSAPH Rep. 2, I-11; Modified: CSAPH Rep. 7, A-12; Modified: CSAPH Rep. 2, I-12; Modified: CSAPH Rep. 8, A-13; Modified in

lieu of Res. 912, I-13; Modified: CSAPH Rep. 3, A-14; Modified: CSAPH Rep. 2, I-15; Appended: CSAPH Rep. 04, I-17; Modified: CSAPH Rep. 02, A-18)

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

(8) RESOLUTION 107 - INVESTIGATE MEDICARE PART D – INSURANCE COMPANY UPCHARGE

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 107 be amended by addition and deletion to read as follows:

~~RESOLVED, That our American Medical Association investigate Medicare Part D rules which allow providers to keep up to 5% more than their actual cost of providing pharmacy prescription services while at the same time they are eligible to get paid by Centers for Medicare and Medicaid Services reinsurance rules for certain losses. (Directive to Take Action)~~

RESOLVED, That our AMA support a US Government Accountability Office (GAO) study of Medicare Part D plan risk assessment behaviors and strategies, and their impact on direct subsidy, reinsurance subsidy and risk corridor payments. (Directive to Take Action)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 107 be adopted as amended.

HOD ACTION: Resolution 107 adopted as amended.

Resolution 107 asks that our AMA investigate Medicare Part D rules which allow providers to keep up to 5% more than their actual cost of providing pharmacy prescription services while at the same time they are eligible to get paid by Centers for Medicare and Medicaid Services reinsurance rules for certain losses.

Your Reference Committee heard mixed testimony on Resolution 107. A speaker raised concerns about whether the AMA would be the appropriate entity to conduct the investigation called for in Resolution 107. As such, your Reference Committee is offering an amendment to bring the study under the auspices of the US Government Accountability Office. Accordingly, your Reference Committee recommends that Resolution 107 be adopted as amended.

(9) RESOLUTION 113 - ENSURING ACCESS TO STATEWIDE COMMERCIAL HEALTH PLANS
RESOLUTION 114 - ENSURING ACCESS TO NATIONWIDE COMMERCIAL HEALTH PLANS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the following alternate resolution be adopted in lieu of Resolutions 113 and 114:

RESOLVED, That our AMA study the impacts of various approaches that offer a public option in addition to current sources of coverage, private or public, including but not limited to a Medicare buy-in; a public option offered on health insurance exchanges; and buying into either the Federal Employees Health Benefits Program or a state employee health plan (Directive to Take Action); and be it further

RESOLVED, That our AMA reaffirm Policy H-165.838 addressing a public option, which states that insurance coverage options offered in a health insurance exchange be self-supporting; have uniform solvency requirements; not receive special advantages from government subsidies; include payment rates established through meaningful negotiations and contracts; not require provider participation; and not restrict enrollees' access to out-of-network physicians (Reaffirm HOD Policy).

Amendment offered during floor consideration: RESOLVED, That our AMA ~~study the impacts of~~ support various approaches that offer a public option in addition to current sources of coverage, private or public, including but not limited to: (a) (i) a Medicare buy-in; (ii) a public option offered on health insurance exchanges; and (iii) buying into either the Federal Employees Health Benefits Program or a state employee health plan~~,~~; and (b) study the options to effectively implement such approaches (Directive to Take Action); and be it further

HOD ACTION: Alternate resolution, amendment and Resolutions 113 and 114 referred.

Resolution 113 asks that our AMA study the concept of offering state employee health plans to every state resident, including exchange participants qualifying for federal subsidies, and report back to the House of Delegates this year; and advocate that State Employees Health Benefits Program health insurance plans be subject to all fully insured state law requirements on prompt payment, fairness in contracting, network adequacy,

limitations or restrictions against high deductible health plans, retrospective audits and reviews, and medical necessity.

Resolution 114 asks that our AMA advocate that Federal Employees Health Benefits Program health insurance plans should become available to everyone to purchase at actuarially appropriate premiums as well as be eligible for federal premium tax credits; and advocate that Federal Employees Health Benefits Program health insurance plans be subject to all fully insured state law requirements on prompt payment, fairness in contracting, network adequacy, limitations or restrictions against high deductible health plans, retrospective audits and reviews, and medical necessity.

Your Reference Committee heard generally supportive testimony on Resolution 113, and calls for referral for Resolution 114. A member of Council on Medical Service welcomed referral of both resolutions for study, and suggested broadening the study to incorporate other approaches to a public option as outlined in the amendment offered by the American College of Physicians (ACP) during discussion of Council on Medical Service Report 2. Your Reference Committee agrees, and believes that the impacts of the various options outlined in Resolutions 113 and 114, and outlined in the ACP amendment, must be assessed. Such a study can analyze the impacts of various public option proposals on coverage rates, affordability, health plan choice, the Medicare Trust Fund, and crowd-out from private to public coverage. Your Reference Committee believes that such a comprehensive study will be helpful in guiding future AMA policy development pertaining to health system reform. Accordingly, your Reference Committee recommends adoption of an alternate resolution in lieu of Resolutions 113 and 114.

H-165.838 Health System Reform Legislation
1. Our American Medical Association is committed to working with Congress, the Administration, and other stakeholders to achieve enactment of health system reforms that include the following seven critical components of AMA policy: a. Health insurance coverage for all Americans b. Insurance market reforms that expand choice of affordable coverage and eliminate denials for pre-existing conditions or due to arbitrary caps c. Assurance that health care decisions will remain in the hands of patients and their physicians, not insurance companies or government officials d. Investments and incentives for quality improvement and prevention and wellness initiatives e. Repeal of the Medicare physician payment formula that triggers steep cuts and threaten seniors' access to care f. Implementation of medical liability reforms to reduce the cost of defensive medicine g. Streamline and standardize insurance claims processing requirements to eliminate unnecessary costs and administrative burdens 2. Our American Medical Association advocates that elimination of denials due to pre-existing conditions is understood to include rescission of insurance coverage for reasons not related to fraudulent representation. 3. Our American Medical Association House of Delegates supports AMA leadership in their unwavering and bold efforts to promote AMA policies for health system reform in the United States. 4. Our American Medical Association supports health system reform alternatives that are consistent with AMA policies concerning pluralism, freedom of choice, freedom of practice, and universal access for patients. <u>5. AMA policy is that insurance coverage options offered in a health insurance exchange be self-supporting, have uniform solvency requirements; not receive special advantages</u>

from government subsidies; include payment rates established through meaningful negotiations and contracts; not require provider participation; and not restrict enrollees' access to out-of-network physicians. 6. Our AMA will actively and publicly support the inclusion in health system reform legislation the right of patients and physicians to privately contract, without penalty to patient or physician. 7. Our AMA will actively and publicly oppose the Independent Medicare Commission (or other similar construct), which would take Medicare payment policy out of the hands of Congress and place it under the control of a group of unelected individuals. 8. Our AMA will actively and publicly oppose, in accordance with AMA policy, inclusion of the following provisions in health system reform legislation: a. Reduced payments to physicians for failing to report quality data when there is evidence that widespread operational problems still have not been corrected by the Centers for Medicare and Medicaid Services b. Medicare payment rate cuts mandated by a commission that would create a double-jeopardy situation for physicians who are already subject to an expenditure target and potential payment reductions under the Medicare physician payment system c. Medicare payments cuts for higher utilization with no operational mechanism to assure that the Centers for Medicare and Medicaid Services can report accurate information that is properly attributed and risk-adjusted d. Redistributed Medicare payments among providers based on outcomes, quality, and risk-adjustment measurements that are not scientifically valid, verifiable and accurate e. Medicare payment cuts for all physician services to partially offset bonuses from one specialty to another f. Arbitrary restrictions on physicians who refer Medicare patients to high quality facilities in which they have an ownership interest 9. Our AMA will continue to actively engage grassroots physicians and physicians in training in collaboration with the state medical and national specialty societies to contact their Members of Congress, and that the grassroots message communicate our AMA's position based on AMA policy. 10. Our AMA will use the most effective media event or campaign to outline what physicians and patients need from health system reform. 11. AMA policy is that national health system reform must include replacing the sustainable growth rate (SGR) with a Medicare physician payment system that automatically keeps pace with the cost of running a practice and is backed by a fair, stable funding formula, and that the AMA initiate a "call to action" with the Federation to advance this goal. 12. AMA policy is that 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. 13. AMA policy is that effective medical liability reform that will significantly lower health care costs by reducing defensive medicine and eliminating unnecessary litigation from the system should be part of any national health system reform. (Sub. Res. 203, I-09; Reaffirmation A-10; Reaffirmed in lieu of Res. 102, A-10; Reaffirmed in lieu of Res. 228, A-10; Reaffirmed: CMS Rep. 2, I-10; Reaffirmed: Sub. Res. 222, I-10; Reaffirmed: CMS Rep. 9, A-11; Reaffirmation A-11; Reaffirmed: CMS Rep. 6, I-11; Reaffirmed in lieu of Res. 817, I-11; Reaffirmation I-11; Reaffirmation A-12; Reaffirmed in lieu of Res. 108, A-12; Reaffirmed: Res. 239, A-12; Reaffirmed: Sub. Res. 813, I-13; Reaffirmed: CMS Rep. 9, A-14; Reaffirmation A-15; Reaffirmed in lieu of Res. 215, A-15; Reaffirmation: A-17; Reaffirmed in lieu of: Res. 712, A-17; Reaffirmed in lieu of: Res. 805, I-17; Reaffirmed: CMS Rep. 03, A-18)

(10) RESOLUTION 115 - SAFETY OF DRUGS APPROVED BY OTHER COUNTRIES
RESOLUTION 129 - THE BENEFITS OF IMPORTATION OF INTERNATIONAL PHARMACEUTICAL MEDICATIONS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the following alternate resolution be adopted in lieu of Resolutions 115 and 129:

RESOLVED, That our AMA support the personal importation of prescription drugs only if:

a. patient safety can be assured;
b. product quality, authenticity and integrity can be assured;
c. prescription drug products are subject to reliable, "electronic" track and trace technology; and
d. prescription drug products are obtained directly from a licensed foreign pharmacy, located in a country that has statutory and/or regulatory standards for the approval and sale of prescription drugs that are comparable to the standards in the United States (New HOD Policy); and be it further

RESOLVED, That our AMA reaffirm Policy D-100.983, which guides AMA advocacy with respect to the prescription drug importation by wholesalers and pharmacies (Reaffirm HOD Policy); and be it further

RESOLVED, That our AMA reaffirm D-100.985, which states that our AMA will continue to actively oppose illegal drug diversion, illegal Internet sales of drugs, illegal importation of drugs, and drug counterfeiting (Reaffirm HOD Policy).

HOD ACTION: Alternate resolution adopted in lieu of Resolutions 115 and 129.

Resolution 115 asks that our AMA compare the results of our US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) approval processes in terms of determining the safety and efficacy of pharmaceuticals using whatever data is available in order to determine whether the health of the citizens of the United States would be at risk if drugs approved by the EMA were imported and used as compared to the FDA; and estimate what the reduction in the cost of medications would be for our patients if they were allowed to import EMA certified medications for use in the United States and thereby increasing competition for some of our current expensive pharmaceuticals.

Resolution 129 asks that our AMA study the implications of prescription drug importation for personal use and wholesale prescription drug purchase across our southern and northern borders.

Your Reference Committee heard generally supportive testimony on the intent of Resolutions 115 and 129. A representative from the US Food and Drug Administration raised significant concerns with Resolution 115 pertaining to patient safety, drug quality and integrity, and innovation and drug development. A member of the Council on Legislation offered an amendment that would establish AMA policy on the personal importation of prescription drugs that would apply to potential legislation addressing importation from Canada, Mexico, European countries and other countries. The member of the Council on Legislation noted that existing Policy D-100.983 blanketly addresses importation by wholesalers and pharmacies. The Council on Medical Service strongly supported the COL amendment. Your Reference Committee agrees that the COL amendment builds off of existing AMA policy with respect to prescription drug importation, and ensures that our policy is able to be used to evaluate state and federal proposals on importation as they are introduced, regardless of countries included in the proposals. Accordingly, your Reference Committee recommends adoption of an alternate resolution in lieu of Resolutions 115 and 129.

D-100.983 Prescription Drug Importation and Patient Safety
Our AMA will:(1) support the legalized importation of prescription drug products by wholesalers and pharmacies only if: (a) all drug products are Food and Drug Administration (FDA)-approved and meet all other FDA regulatory requirements, pursuant to United States laws and regulations; (b) the drug distribution chain is "closed," and all drug products are subject to reliable, "electronic" track and trace technology; and (c) the Congress grants necessary additional authority and resources to the FDA to ensure the authenticity and integrity of prescription drugs that are imported; (2) oppose personal importation of prescription drugs via the Internet until patient safety can be assured; (3) review the recommendations of the forthcoming report of the Department of Health and Human Services (HHS) Task Force on Drug Importation and, as appropriate, revise its position on whether or how patient safety can be assured under legalized drug importation; (4) educate its members regarding the risks and benefits associated with drug importation and reimportation efforts; (5) support the in-person purchase and importation of Health Canada-approved prescription drugs obtained directly from a licensed Canadian pharmacy when product integrity can be assured, provided such drugs are for personal use and of a limited quantity; and (6) advocate for an increase in funding for the US Food and Drug Administration to administer and enforce a program that allows the in-person purchase and importation of prescription drugs from Canada, if the integrity of prescription drug products imported for personal use can be assured. (BOT Rep. 3, I-04; Reaffirmation A-09; Reaffirmed in lieu of: Res. 817, I-16; Appended: CMS Rep. 01, I-18)

D-100.985 Federal Regulation and Computerized Tracking of Pharmaceuticals During Shipping and Handling from Manufacture Until Ultimately Received by Patient
Our AMA will: (1) continue to actively oppose illegal drug diversion, illegal Internet sales of drugs, illegal importation of drugs, and drug counterfeiting; and (2) work with the Congress, the Food and Drug Administration, the Drug

Enforcement Administration, and other federal agencies, the pharmaceutical industry, and other stakeholders to ensure that these illegal activities are minimized. (Res. 501, A-04; Reaffirmation I-06; Reaffirmed: BOT Rep. 06, A-16; Reaffirmed: CMS Rep. 01, I-18)

(11) RESOLUTION 117 - SUPPORT FOR MEDICARE DISABILITY COVERAGE OF CONTRACEPTION FOR NON-CONTRACEPTIVE USE

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 117 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association work with the Centers for Medicare and Medicaid Services and other stakeholders to include coverage for all US Food and Drug Administration-approved ~~contraception~~ contraceptive methods for contraceptive and non-contraceptive use for all patients covered by Medicare, regardless of eligibility pathway (age or disability). (Directive to Take Action)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 117 be adopted as amended.

HOD ACTION: Resolution 117 adopted as amended with a change in title.

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that the title of Resolution 117 be changed to read as follows:

SUPPORT FOR MEDICARE COVERAGE OF CONTRACEPTIVE METHODS

Resolution 117 asks that our AMA work with the Centers for Medicare and Medicaid Services and other stakeholders to include coverage for all US Food and Drug Administration-approved contraception for non-contraceptive use for patients covered by Medicare.

Your Reference Committee heard generally supportive testimony on Resolution 117. A member of the Council on Medical Service testified that AMA policy already addresses the intent of Resolution 117. Several speakers testified in support of Resolution 117, emphasizing the importance of AMA action on this issue. An amendment was offered to

broaden the scope of Resolution 117. Your Reference Committee accepts the amendment and recommends Resolution 117 be adopted as amended.

(12) RESOLUTION 119 - RETURNING LIQUID OXYGEN TO FEE SCHEDULE PAYMENT

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 119 be amended by deletion to read as follows:

RESOLVED, That our American Medical Association support policy to remove liquid oxygen from the competitive bidding system and return payments for liquid oxygen to a Medicare fee schedule basis. (New HOD Policy)~~; and be it further~~

~~RESOLVED, That our AMA convey its patient quality and access concerns for Medicare beneficiaries obtaining insurance coverage for liquid oxygen in comments to the Centers for Medicare and Medicaid Services, including the forthcoming proposed rule, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) for Calendar Year 2020. (Directive to Take Action)~~

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 119 be adopted as amended.

HOD ACTION: Resolution 119 adopted as amended.

Resolution 119 asks that our AMA support policy to remove liquid oxygen from the competitive bidding system and return payments for liquid oxygen to a Medicare fee schedule basis; and convey its patient quality and access concerns for Medicare beneficiaries obtaining insurance coverage for liquid oxygen in comments to the Centers for Medicare and Medicaid Services (CMS), including the forthcoming proposed rule, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) for Calendar Year 2020.

Testimony on Resolution 119 was supportive. The sponsor of Resolution 119 testified, emphasizing the importance of returning liquid oxygen to a Fee For Service schedule. Consistent with this testimony, your Reference Committee suggests an amendment to delete reference to specific advocacy efforts to allow the AMA to advocate for any avenues as appropriate. Accordingly, your Reference Committee recommends that Resolution 119 be adopted as amended.

(13) RESOLUTION 122 - REIMBURSEMENT FOR TELEMEDICINE VISITS

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 122 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association work with third-party payers, ~~and~~ the Centers for Medicare and Medicaid Services, Congress and interested state medical associations to provide coverage and reimbursement ~~for both synchronous and asynchronous telemedicine services~~ for telehealth to ensure ~~encourage~~ increased access and use of these services by patients and physicians.

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 122 be adopted as amended.

HOD ACTION: Resolution 122 adopted as amended with a change in title.

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that the title of Resolution 122 be changed to read as follows:

REIMBURSEMENT FOR TELEHEALTH

Resolution 122 asks that our AMA work with third-party payers and the Centers for Medicare and Medicaid Services at the national level to provide reimbursement for both synchronous and asynchronous telemedicine services to encourage increased access and use of these services by patients and physicians.

Your Reference Committee heard highly supportive testimony on Resolution 122. A member of the Council on Legislation testified that while the AMA has overarching policy guiding the coverage for and payment of telemedicine adopted by the House in 2014, the AMA does need to advocate that commercial payers provide payment parity for physicians who offer in-person and virtual services. The member of the Council on Legislation also noted that the impediment to synchronous telehealth is not the Centers for Medicare and Medicaid Services – it is the Social Security Act. As such, the Council member offered an amendment to include Congress and state medical associations, as well as use the term “telehealth” to be all-encompassing of synchronous and asynchronous telemedicine as well as digital health services, and remove confusion in the terms used.

(14) RESOLUTION 124 - INCREASED AFFORDABILITY AND ACCESS TO HEARING AIDS AND RELATED CARE
RESOLUTION 120 - MEDICARE COVERAGE OF HEARING AIDS

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the third Resolve of Resolution 124 be amended by deletion to read as follows:

RESOLVED, That our AMA support the availability of over-the-counter hearing aids for the treatment of ~~age-related~~ mild-to-moderate hearing loss. (New HOD Policy)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 124 be adopted as amended in lieu of Resolution 120.

HOD ACTION: Resolution 124 adopted as amended in lieu of Resolution 120.

Resolution 120 asks that our AMA urge Medicare to cover some or all of the costs of a "reasonable" device for both ears if a patient has had an audiological exam that identifies the need, and for Medicare to identify a vendor, or vendors, of hearing devices that produce a quality product without an exorbitant retail price.

Resolution 124 asks that our AMA support policies that increase access to hearing aids and other technologies and services that alleviate hearing loss and its consequences for the elderly; encourage increased transparency and access for hearing aid technologies through itemization of audiologic service costs for hearing aids; and support the availability of over-the-counter hearing aids for the treatment of age-related mild-to-moderate hearing loss.

Testimony on Resolution 124 was supportive, and testimony on Resolution 120 was mixed. A member of the Council on Medical Service testified in support of adopting Resolution 124 in lieu of Resolution 120, explaining that the Council recently issued a report on hearing aid coverage that specifically addressed the intent of Resolution 120 and is consistent with the intent of Resolution 124. The member from the Council on Medical Service explained that in their report, the Council explicitly considered and decided not to recommend that the AMA support Medicare coverage of hearing aids. Other speakers testified that Resolution 124 offers a novel approach to the issue highlighted by both Resolutions 120 and 124.

Your Reference Committee believes that Resolution 124 is consistent with existing AMA policy regarding improving coverage of and access to hearing aids, and suggests an amendment to broaden the impact of Resolution 124. Moreover, your Reference Committee believes that Resolution 124 accomplishes the purpose of Resolution 120.

Accordingly, your Reference Committee recommends that Resolution 124 be adopted as amended, and that amended Resolution 124 be adopted in lieu of Resolution 120.

(15) RESOLUTION 126 - ENSURING PRESCRIPTION DRUG PRICE TRANSPARENCY FROM RETAIL PHARMACIES

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 126 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association amend policy H-110.991, "Price of Medicine," by addition and deletion as follows:

Our AMA: (~~1) work with relevant organizations to advocate for increased transparency through access to meaningful and relevant information about medication price and out-of-pocket costs for prescription medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare's drug-pricing dashboard; (1)~~ advocates that pharmacies be required to list the full retail price of the prescription on the receipt along with the co-pay that is required in order to better inform our patients of the price of their medications; (2) will pursue legislation requiring pharmacies, pharmacy benefit managers and health plans to inform patients of the actual cash price as well as the formulary price of any medication prior to the purchase of the medication; (3) opposes provisions in pharmacies' contracts with pharmacy benefit managers that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price; (4) will disseminate model state legislation to promote drug price and cost transparency ~~and to prohibit "clawbacks" and standard gag clauses in contracts between pharmacies and pharmacy benefit managers (PBMs) that bar pharmacists from telling consumers about less-expensive options for purchasing their medication~~; and (5) supports physician education regarding drug price and cost transparency, manufacturers' pricing practices, and challenges patients may encounter at the pharmacy point-of-sale. (6) work with relevant organizations to advocate for increased transparency through access to meaningful and relevant information about medication price and out-of-pocket costs for prescription medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare's drug-pricing dashboard. (Modify Current HOD Policy)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 126 be adopted as amended.

HOD ACTION: Resolution 126 adopted as amended.

Resolution 126 asks that our AMA amend Policy H-110.991 as follows: Our AMA: (1) work with relevant organizations to advocate for increased transparency through access to meaningful and relevant information about medication price and out-of-pocket costs for prescription medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare's drug-pricing dashboard; ~~(1) advocates that pharmacies be required to list the full retail price of the prescription on the receipt along with the co-pay that is required in order to better inform our patients of the price of their medications;~~(2) will pursue legislation requiring pharmacies, pharmacy benefit managers and health plans to inform patients of the actual cash price as well as the formulary price of any medication prior to the purchase of the medication; (3) opposes provisions in pharmacies' contracts with pharmacy benefit managers that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price; (4) will disseminate model state legislation to promote drug price and cost transparency ~~and to prohibit "clawbacks" and standard gag clauses in contracts between pharmacies and pharmacy benefit managers (PBMs) that bar pharmacists from telling consumers about less-expensive options for purchasing their medication~~; and (5) supports physician education regarding drug price and cost transparency, manufacturers' pricing practices, and challenges patients may encounter at the pharmacy point-of-sale.

Your Reference Committee heard highly supportive testimony on Resolution 126. An amendment was offered to reinstate language that our AMA will disseminate model state legislation to prohibit "clawbacks." Your Reference Committee accepts the amendment. Your Reference Committee also is offering an amendment to retain the original first clause of Policy H-110.991, while also accepting the new language proffered in Resolution 126. Accordingly, your Reference Committee recommends that Resolution 126 be adopted as amended.

(16) RESOLUTION 131 - UPDATE PRACTICE EXPENSE COMPONENT OF RELATIVE VALUE UNITS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that that Resolution 131 be referred for decision.

HOD ACTION: Resolution 131 referred for decision.

Resolution 131 asks that our AMA pursue efforts to update resource-based relative value unit practice expense methodology so it accurately reflects current physician practice costs, with a report back at the AMA House of Delegates 2019 Interim Meeting.

Your Reference Committee heard mixed testimony on Resolution 131. A member of the Council on Medical Service recommended reaffirmation of existing Policy D-330.902 in

lieu of the resolution. This policy directive specifically calls for our AMA to "urge CMS to update the data used to calculate the practice expense component of the Medicare physician fee schedule by administering a physician practice survey (similar to the Physician Practice Information Survey administered in 2007-2008) every five years, and that this survey collect data to ensure that all physician practice costs are captured." Further, the policy calls for our AMA to "collect data and conduct research to facilitate adjustments to the portion of the Medicare budget allocated to physician services that more accurately reflects practice costs and changes in health care delivery." The CMS attested that this study is currently underway.

The authors provided ardent testimony that the AMA should conduct a new study of current physician practice costs for its members, since hospitals do so annually and have seen increases in payments. Further, physicians have borne the entire burden of budget neutrality while all stakeholders should be accountable. Compelling testimony was provided by the AMA's representative to the RVS Update Committee (RUC) which acknowledged the inequitableness in a conversion factor that is not increasing while costs are, but explained that a new survey would only lead to redistribution of funds within the payment schedule. As the Medicare physician payment schedule is a budget neutral system, a survey to update the practice expense relative values would lead only to redistribution and not to an overall increase in physician payment.

Your Reference Committee acknowledges the importance and complexity of this issue. Moreover, the $5 million fiscal note deserves consideration by the AMA Board of Trustees. For these reasons, your Reference Committee recommends that Resolution 131 be referred for decision.

(17) RESOLUTION 101 - HEALTH HAZARDS OF HIGH DEDUCTIBLE INSURANCE
RESOLUTION 125 - MITIGATING THE NEGATIVE EFFECTS OF HIGH-DEDUCTIBLE HEALTH PLANS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the Policies H-165.846, D-185.979 and H-165.828 be reaffirmed in lieu of Resolutions 101 and 125.

HOD ACTION: Policies H-165.846, D-185.979 and H-165.828 reaffirmed in lieu of Resolution 101.

Resolution 125 referred.

Resolution 101 asks that our AMA support health insurance deductibles of not more than $1,000 for an individual per year, especially to patients with significant chronic disease.

Resolution 125 asks that our AMA advocate for legislation or regulation specifying that codes for outpatient evaluation and management services, including initial and established patient office visits, be exempt from deductible payments.

Your Reference Committee heard mixed testimony on Resolutions 101 and 125. Testimony stressed that high deductibles and cost-sharing requirements can serve as barriers to patients accessing the care they need. A member of the Council on Medical Service testified that the approaches put forward in Resolutions 101 and 125 would have the unintended consequence of increasing premiums, potentially making health insurance coverage unaffordable for many. Furthermore, the Council member stated that both resolutions would severely limit patient choice of health plan, and Resolution 101 in particular would hamper patient use of health savings accounts. Your Reference Committee notes that, in addition, Resolution 125 could cause cost-sharing requirements for benefits not included in the resolution to increase, in order to maintain a plan's actuarial value (the percentage of total average costs for covered benefits that a plan will cover).

The Council member continued that existing policy addresses the spirit of Resolutions 101 and 125. In addition, the recommendations of Council on Medical Service Report 2 being considered at this meeting also call for more people to be eligible for cost-sharing reductions for ACA exchange coverage, and for such reductions to be more generous in size. Policy H-165.846 states 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 D-185.979 supports innovations that expand access to affordable care, including changes needed to allow high-deductible health plans paired with health savings accounts to provide pre-deductible coverage for preventive and chronic care management services. In addition, for low-income individuals who qualify for cost-sharing reductions who instead enroll in a bronze plan with higher out-of-pocket costs, Policy H-165.828 encourages the development of demonstration projects to allow individuals eligible for cost-sharing subsidies, who forego these subsidies by enrolling in a bronze plan, to have access to a health savings account partially funded by an amount determined to be equivalent to the cost-sharing subsidy. This change would help affected individuals meet the deductibles and other cost-sharing obligations of their bronze plan.

Your Reference Committee agrees that existing policy addresses the intent of Resolutions 101 and 125. As such, your Reference Committee recommends the reaffirmation of Policies H-165.846, D-185.979 and H-165.828 in lieu of Resolutions 101 and 125.

> H-165.828 Health Insurance Affordability
> 1. Our AMA supports modifying the eligibility criteria for premium credits and cost-sharing subsidies for those offered employer-sponsored coverage by lowering the threshold that determines whether an employee's premium contribution is affordable to that which applies to the exemption from the individual mandate of the Affordable Care Act (ACA). 2. Our AMA supports legislation or regulation, whichever is relevant, to fix the ACA's "family glitch," thus determining the affordability of employer-sponsored coverage with respect to the cost of family-based or employee-only coverage. 3. Our AMA encourages the development of demonstration projects to allow individuals eligible for cost-sharing subsidies, who forego these subsidies by enrolling in a bronze plan, to have access to a health savings account (HSA) partially funded by an amount determined to be equivalent to the cost-sharing subsidy. 4. Our AMA supports capping the tax exclusion for employment-based health insurance as a funding

stream to improve health insurance affordability, including for individuals impacted by the inconsistency in affordability definitions, individuals impacted by the "family glitch," and individuals who forego cost-sharing subsidies despite being eligible. 5. Our AMA supports additional education regarding deductibles and cost-sharing at the time of health plan enrollment, including through the use of online prompts and the provision of examples of patient cost-sharing responsibilities for common procedures and services. 6. Our AMA supports efforts to ensure clear and meaningful differences between plans offered on health insurance exchanges. 7. Our AMA supports clear labeling of exchange plans that are eligible to be paired with a Health Savings Account (HSA) with information on how to set up an HSA. (CMS Rep. 8, I-15; Reaffirmed in lieu of: Res. 121, A-16; Reaffirmation: A-17)

H-165.846 Adequacy of Health Insurance Coverage Options
1. Our AMA supports the following principles to guide in the evaluation of the adequacy of health insurance coverage options: A. Any insurance pool or similar structure designed to enable access to age-appropriate health insurance coverage must include a wide variety of coverage options from which to choose. B. Existing federal guidelines regarding types of health insurance coverage (e.g., Title 26 of the US Tax Code and Federal Employees Health Benefits Program [FEHBP] regulations) should be used as a reference when considering if a given plan would provide meaningful coverage. C. 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. D. Mechanisms must be in place to educate patients and assist them in making informed choices, including ensuring transparency among all health plans regarding covered services, cost-sharing obligations, out-of-pocket limits and lifetime benefit caps, and excluded services. 2. Our AMA advocates that the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program be used as the model for any essential health benefits package for children. 3. Our AMA: (a) opposes the removal of categories from the essential health benefits (EHB) package and their associated protections against annual and lifetime limits, and out-of-pocket expenses; and (b) opposes waivers of EHB requirements that lead to the elimination of EHB categories and their associated protections against annual and lifetime limits, and out-of-pocket expenses. (CMS Rep. 7, A-07; Reaffirmation I-07; Reaffirmation A-09; Reaffirmed: Res. 103, A-09; Reaffirmation I-09; Reaffirmed: CMS Rep. 3, I-09; Reaffirmed: CMS Rep. 2, A-11; Appended: CMS Rep. 2, A-11; Reaffirmed in lieu of Res. 109, A-12; Reaffirmed: CMS Rep. 1, I-12; Reaffirmed: CMS Rep. 3, A-13; Reaffirmed in lieu of Res. 812, I-13; Reaffirmed: CMS Rep. 6, I-14; Reaffirmed: CMS Rep. 6, I-15; Appended: CMS Rep. 04, I-17)

D-185.979 Aligning Clinical and Financial Incentives for High-Value Care
1. Our AMA supports Value-Based Insurance Design (VBID) plans designed in accordance with the tenets of "clinical nuance," recognizing that (a) medical services may differ in the amount of health produced, and (b) the clinical benefit derived from a specific service depends on the person receiving it, as well as when, where, and by whom the service is provided. 2. Our AMA supports initiatives that align provider-facing financial incentives created through payment reform and patient-facing financial incentives created through benefit design

reform, to ensure that patient, provider, and payer incentives all promote the same quality care. Such initiatives may include reducing patient cost-sharing for the items and services that are tied to provider quality metrics. 3. Our AMA will develop coding guidance tools to help providers appropriately bill for zero-dollar preventive interventions and promote common understanding among health care providers, payers, patients, and health care information technology vendors regarding what will be covered at given cost-sharing levels. 4. Our AMA will develop physician educational tools that prepare physicians for conversations with their patients about the scope of preventive services provided without cost-sharing and instances where and when preventive services may result in financial obligations for the patient. 5. Our AMA will continue to support requiring private health plans to provide coverage for evidence-based preventive services without imposing cost-sharing (such as co-payments, deductibles, or coinsurance) on patients. 6. Our AMA will continue to support implementing innovative VBID programs in Medicare Advantage plans. 7. Our AMA supports legislative and regulatory flexibility to accommodate VBID that (a) preserves health plan coverage without patient cost-sharing for evidence-based preventive services; and (b) allows innovations that expand access to affordable care, including changes needed to allow High Deductible Health Plans paired with Health Savings Accounts to provide pre-deductible coverage for preventive and chronic care management services. 8. Our AMA encourages national medical specialty societies to identify services that they consider to be high-value and collaborate with payers to experiment with benefit plan designs that align patient financial incentives with utilization of high-value services. (Joint CMS CSAPH Rep. 01, I-18)

(18) RESOLUTION 109 - PART A MEDICARE PAYMENT TO PHYSICIANS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Policies D-390.969 and D-330.902 be reaffirmed in lieu of Resolution 109.

HOD ACTION: Resolution 109 adopted.

Resolution 109 asks that our AMA work for enactment of legislation to direct cash payments from Part A Medicare to physicians in direct proportion to demonstrated savings that are made in Part A Medicare through the efforts of physicians.

Your Reference Committee heard testimony in favor of reaffirmation of Resolution 109. Significant testimony from the Council on Medical Service highlighted that existing policy addresses the intent of the resolution. The Council's report from the last meeting (D-330.902) recommended a study to document the role that physicians have played in reducing Medicare spending, as noted in the third Whereas clause, and existing policy on parity in Medicare reimbursement directly aligns with the Resolved clause. The authors expressed that existing policy should be made a top priority of the Association. Your Reference Committee empathizes but agrees that existing policy is sufficient for supporting continued AMA efforts in this important area. As such, your Reference

Committee recommends that Policies D-390.969 and D-330.902 be reaffirmed in lieu of Resolution 109.

D-390.969 Parity in Medicare Reimbursement
Our AMA will continue its comprehensive advocacy campaign to: (1) repeal the reductions in Medicare payment for imaging services furnished in physicians' offices, as mandated by the Deficit Reduction Act of 2005; (2) pass legislation allowing physicians to share in Medicare Part A savings that are achieved when physicians provide medical care that results in fewer in-patient complications, shorter lengths-of-stays, and fewer hospital readmissions; and (3) advocate for other mechanisms to ensure adequate payments to physicians, such as balance billing and gainsharing. (Referred for decision Res. 236, A-06; Reaffirmation I-08; Modified: BOT Rep. 09, A-18; Reaffirmed in lieu of: Res. 823, I-18)

D-330.902 The Site-of-Service Differential
1. Our AMA supports Medicare payment policies for outpatient services that are site-neutral without lowering total Medicare payments. 2. Our AMA supports Medicare payments for the same service routinely and safely provided in multiple outpatient settings (e.g., physician offices, HOPDs, and ASCs) that are based on sufficient and accurate data regarding the actual costs of providing the service in each setting. 3. Our AMA will urge CMS to update the data used to calculate the practice expense component of the Medicare physician fee schedule by administering a physician practice survey (similar to the Physician Practice Information Survey administered in 2007-2008) every five years, and that this survey collect data to ensure that all physician practice costs are captured. 4. Our AMA encourages CMS to both: a) base disproportionate share hospital payments and uncompensated care payments to hospitals on actual uncompensated care data; and b) study the costs to independent physician practices of providing uncompensated care. 5. Our AMA will collect data and conduct research both: a) to document the role that physicians have played in reducing Medicare spending; and b) to facilitate adjustments to the portion of the Medicare budget allocated to physician services that more accurately reflects practice costs and changes in health care delivery. (CMS Rep. 04, I-18)

(19) RESOLUTION 111 - PRACTICE OVERHEAD EXPENSE AND THE SITE-OF-SERVICE DIFFERENTIAL
RESOLUTION 132 (LATE RESOLUTION 1003) - SITE OF SERVICE DIFFERENTIAL

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Policies D-330.902, D-390.969, H-240.993 and H-400.957 be reaffirmed in lieu of Resolution 111 and Late Resolution 132.

HOD ACTION: Resolutions 111 and 132 referred for decision.

Resolution 111 asks that our AMA appeal to the US Congress for legislation to direct the Centers for Medicare and Medicaid Services (CMS) to eliminate any site-of-service differential payments to hospitals for the same service that can safely be performed in a doctor's office; appeal to the US Congress for legislation to direct CMS in regards to any savings to Part B Medicare, through elimination of the site-of-service differential payments to hospitals, (for the same service that can safely be performed in a doctor's office), be distributed to all physicians who participate in Part B Medicare, by means of improved payments for office-based Evaluation and Management Codes, so as to immediately redress underpayment to physicians in regards to overhead expense; and appeal to the US Congress for legislation to direct CMS to make Medicare payments for the same service routinely and safely provided in multiple outpatient settings (e.g., physician offices, HOPDs and ASCs) that are based on sufficient and accurate data regarding the actual costs of providing the service in each setting.

Resolution 132 (Late Resolution 1003) asks that our American Medical Association advocate for site of service payment equalization to be calculated in a manner that both enhances physician reimbursement while maintaining hospital rates for physician services at an objectively justifiable level, including but not limited to the filing of amicus briefs in relevant lawsuits as determined appropriate by the Office of General Counsel.

Your Reference Committee heard mixed testimony on Resolution 111 and Resolution 132 which spoke to the historical inequality between payments for Medicare part A and part B. The majority of testimony favored reaffirmation of existing policies, in particular D-330.992 from CMS Report 4-I-18 "The Site-of-Service Differential." The third resolve clause for Resolution 111 uses language verbatim from this report. Testimony from the authors called for a serious legislative initiative and did not believe that the resolution was redundant. The AMA's representative to the RVS Update Committee (RUC) provided testimony stating that the AMA is already working with the Centers for Medicaid and Medicare Services (CMS) and that the best course of action is reaffirmation. Further, regarding the second resolve of Resolution 111, the CPT recently revised the E/M office visits and the RUC made recommendations to CMS that would be applied across the entire Medicare payment schedule, if adopted. In addition, the AMA submitted an OPPS/ASC comment letter last year which states that savings should be reinvested back into the physician fee schedule but did not specifically point to E/M payments. Regarding Resolution 132, your Reference Committee concurs that current policy is supportive of AMA action in this area including the filing of amicus briefs. For these reasons, your Reference Committee recommends that Policies D-330.902, D-390.969, H-240.993 and H-400.957 be reaffirmed in lieu of Resolution 111 and Resolution 132.

> D-330.902 The Site-of-Service Differential
> 1. Our AMA supports Medicare payment policies for outpatient services that are site-neutral without lowering total Medicare payments. 2. Our AMA supports Medicare payments for the same service routinely and safely provided in multiple outpatient settings (e.g., physician offices, HOPDs, and ASCs) that are based on sufficient and accurate data regarding the actual costs of providing the service in each setting. 3. Our AMA will urge CMS to update the data used to calculate the practice expense component of the Medicare physician fee schedule by administering a physician practice survey (similar to the Physician Practice Information Survey administered in 2007-2008) every five years, and that this

survey collect data to ensure that all physician practice costs are captured. 4. Our AMA encourages CMS to both: a) base disproportionate share hospital payments and uncompensated care payments to hospitals on actual uncompensated care data; and b) study the costs to independent physician practices of providing uncompensated care. 5. Our AMA will collect data and conduct research both: a) to document the role that physicians have played in reducing Medicare spending; and b) to facilitate adjustments to the portion of the Medicare budget allocated to physician services that more accurately reflects practice costs and changes in health care delivery. (CMS Rep. 04, I-18)

D-390.969 Parity in Medicare Reimbursement
Our AMA will continue its comprehensive advocacy campaign to: (1) repeal the reductions in Medicare payment for imaging services furnished in physicians' offices, as mandated by the Deficit Reduction Act of 2005; (2) pass legislation allowing physicians to share in Medicare Part A savings that are achieved when physicians provide medical care that results in fewer in-patient complications, shorter lengths-of-stays, and fewer hospital readmissions; and (3) advocate for other mechanisms to ensure adequate payments to physicians, such as balance billing and gainsharing. (Referred for decision Res. 236, A-06 Reaffirmation I-08 Modified: BOT Rep. 09, A-18 Reaffirmed in lieu of: Res. 823, I-18)

H-240.993 Discontinuance of Federal Funding for Ambulatory Care Centers
The AMA strongly urges more aggressive implementation by HHS of existing provisions in federal legislation calling for equity of reimbursement between services provided by hospitals on an outpatient basis and similar services in physicians' offices. (CMS Rep. B, A-83 Reaffirmed: CLRPD Rep. 1, I-93 Reaffirmation I-98 Reaffirmation I-03 Reaffirmation I-07 Reaffirmed: CMS Rep. 3, A-13 Reaffirmation A-15 Reaffirmed: CMS Rep. 04, I-18)

H-400.957 Medicare Reimbursement of Office-Based Procedures
Our AMA will: (1) encourage CMS to expand the extent and amount of reimbursement for procedures performed in the physician's office, to shift more procedures from the hospital to the office setting, which is more cost effective; (2) seek to have the RBRVS practice expense RVUs reflect the true cost of performing office procedures; and (3) work with CMS to develop consistent regulations to be followed by carriers that include reimbursement for the costs of disposable supplies and surgical tray fees incurred with office-based procedures and surgery. (Sub. Res. 103, I-93 Reaffirmed by Rules & Credentials Cmt., A-96 Reaffirmation A-04 Reaffirmation I-04 Reaffirmed: CMS Rep. 1, A-14 Reaffirmed: CMS Rep. 3, A-14 Reaffirmed in lieu of Res. 216, I-14 Reaffirmed: CMS Rep. 04, I-18)

(20) RESOLUTION 112 - HEALTH CARE FEE TRANSPARENCY

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Policies H-105.988, D-155.987 and H-373.998 be reaffirmed in lieu of Resolution 112.

HOD ACTION: Policies H-105.988, D-155.987 and H-373.998 reaffirmed in lieu of Resolution 112.

Resolution 112 asks that our AMA advocate for federal legislation and/or regulation to require disclosure of hospital prices negotiated with insurance companies in effort to achieve third-party contract transparency; and advocate for federal legislation and/or regulation to require pharmaceutical companies to disclose drug prices in their television (TV) ads in order to provide consumers more choice and control over their healthcare.

There was mixed testimony on Resolution 112. In the introduction of the resolution, the sponsor of Resolution 112 stated that the second resolve of the resolution is indeed a reaffirmation of already existing policy. Further, members of the Council on Medical Service and Council on Legislation called for reaffirmation of existing policy in lieu of Resolution 112 in its entirety. The member of the Council on Medical Service stated that existing policy enables the AMA to advocate in response to the provisions of the 21st Century Cures Act (Cures Act) highlighted by the sponsor of Resolution 112.

In addition, the member of the Council on Legislation underscored that the AMA has engaged in advocacy efforts directly addressing the intent of Resolution 112. For example, the AMA submitted a letter to select U.S. Senators, which provided feedback on Congressional efforts to increase health care price and information transparency to empower patients, improve the quality of health care, and lower health care costs. Furthermore, the AMA submitted a letter to CMS Administrator Seema Verma in response to the proposed rule requiring the disclosure of prescription drug list prices in direct-to-consumer advertisements on television.

Your Reference Committee believes that Resolution 112 is already addressed by existing AMA policy and ongoing advocacy efforts. As such, your Reference Committee recommends that Policies H-105.988, D-155.987 and H-373.998 be reaffirmed in lieu of Resolution 112.

H-105.988 Direct-to-Consumer Advertising (DTCA) of Prescription Drugs and Implantable Devices
1. To support a ban on direct-to-consumer advertising for prescription drugs and implantable medical devices. 2. That until such a ban is in place, our AMA opposes product-claim DTCA that does not satisfy the following guidelines: (a) The advertisement should be indication-specific and enhance consumer education about the drug or implantable medical device, and the disease, disorder, or condition for which the drug or device is used. (b) In addition to creating awareness about a drug or implantable medical device for the treatment or prevention of a disease, disorder, or condition, the advertisement should

convey a clear, accurate and responsible health education message by providing objective information about the benefits and risks of the drug or implantable medical device for a given indication. Information about benefits should reflect the true efficacy of the drug or implantable medical device as determined by clinical trials that resulted in the drug's or device's approval for marketing. (c) The advertisement should clearly indicate that the product is a prescription drug or implantable medical device to distinguish such advertising from other advertising for non-prescription products. (d) The advertisement should not encourage self-diagnosis and self-treatment, but should refer patients to their physicians for more information. A statement, such as "Your physician may recommend other appropriate treatments," is recommended. (e) The advertisement should exhibit fair balance between benefit and risk information when discussing the use of the drug or implantable medical device product for the disease, disorder, or condition. The amount of time or space devoted to benefit and risk information, as well as its cognitive accessibility, should be comparable. (f) The advertisement should present information about warnings, precautions, and potential adverse reactions associated with the drug or implantable medical device product in a manner (e.g., at a reading grade level) such that it will be understood by a majority of consumers, without distraction of content, and will help facilitate communication between physician and patient. (g) The advertisement should not make comparative claims for the product versus other prescription drug or implantable medical device products; however, the advertisement should include information about the availability of alternative non-drug or non-operative management options such as diet and lifestyle changes, where appropriate, for the disease, disorder, or condition. (h) In general, product-claim DTCA should not use an actor to portray a health care professional who promotes the drug or implantable medical device product, because this portrayal may be misleading and deceptive. If actors portray health care professionals in DTCA, a disclaimer should be prominently displayed. (i) The use of actual health care professionals, either practicing or retired, in DTCA to endorse a specific drug or implantable medical device product is discouraged but if utilized, the advertisement must include a clearly visible disclaimer that the health care professional is compensated for the endorsement. (j) The advertisement should be targeted for placement in print, broadcast, or other electronic media so as to avoid audiences that are not age appropriate for the messages involved. (k) In addition to the above, the advertisement must comply with all other applicable Food and Drug Administration (FDA) regulations, policies and guidelines. 3. That the FDA review and pre-approve all DTCA for prescription drugs or implantable medical device products before pharmaceutical and medical device manufacturers (sponsors) run the ads, both to ensure compliance with federal regulations and consistency with FDA-approved labeling for the drug or implantable medical device product. 4. That the Congress provide sufficient funding to the FDA, either through direct appropriations or through prescription drug or implantable medical device user fees, to ensure effective regulation of DTCA. 5. That DTCA for newly approved prescription drug or implantable medical device products not be run until sufficient post-marketing experience has been obtained to determine product risks in the general population and until physicians have been appropriately educated about the drug or implantable medical device. The time interval for this moratorium on DTCA for newly approved drugs or implantable medical devices should be determined by the FDA, in negotiations with the drug or medical device

product's sponsor, at the time of drug or implantable medical device approval. The length of the moratorium may vary from drug to drug and device to device depending on various factors, such as: the innovative nature of the drug or implantable medical device; the severity of the disease that the drug or implantable medical device is intended to treat; the availability of alternative therapies; and the intensity and timeliness of the education about the drug or implantable medical device for physicians who are most likely to prescribe it. 6. That our AMA opposes any manufacturer (drug or device sponsor) incentive programs for physician prescribing and pharmacist dispensing that are run concurrently with DTCA. 7. That our AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical and medical device industries to conduct or fund research on the effect of DTCA, focusing on its impact on the patient-physician relationship as well as overall health outcomes and cost benefit analyses; research results should be available to the public. 8. That our AMA supports the concept that when companies engage in DTCA, they assume an increased responsibility for the informational content and an increased duty to warn consumers, and they may lose an element of protection normally accorded under the learned intermediary doctrine. 9. That our AMA encourages physicians to be familiar with the above AMA guidelines for product-claim DTCA and with the Council on Ethical and Judicial Affairs Ethical Opinion E-9.6.7 and to adhere to the ethical guidance provided in that Opinion. 10. That the Congress should request the Agency for Healthcare Research and Quality or other appropriate entity to perform periodic evidence-based reviews of DTCA in the United States to determine the impact of DTCA on health outcomes and the public health. If DTCA is found to have a negative impact on health outcomes and is detrimental to the public health, the Congress should consider enacting legislation to increase DTCA regulation or, if necessary, to prohibit DTCA in some or all media. In such legislation, every effort should be made to not violate protections on commercial speech, as provided by the First Amendment to the U.S. Constitution. 11. That our AMA supports eliminating the costs for DTCA of prescription drugs as a deductible business expense for tax purposes. 12. That our AMA continues to monitor DTCA, including new research findings, and work with the FDA and the pharmaceutical and medical device industries to make policy changes regarding DTCA, as necessary. 13. That our AMA supports "help-seeking" or "disease awareness" advertisements (i.e., advertisements that discuss a disease, disorder, or condition and advise consumers to see their physicians, but do not mention a drug or implantable medical device or other medical product and are not regulated by the FDA). 14. Our AMA will advocate to the applicable Federal agencies (including the Food and Drug Administration, the Federal Trade Commission, and the Federal Communications Commission) which regulate or influence direct-to-consumer advertising of prescription drugs that such advertising should be required to state the manufacturer’s suggested retail price of those drugs. BOT Rep. 38 and Sub. Res. 513, A-99; Reaffirmed: CMS Rep. 9, Amended: Res. 509, and Reaffirmation I-99; Appended & Reaffirmed: Sub. Res. 503, A-01; Reaffirmed: Res. 522, A-02; Reaffirmed: Res. 914, I-02; Reaffirmed: Sub. Res. 504, A-03; Reaffirmation A-04; Reaffirmation A-05; Modified: BOT Rep. 9, A-06; Reaffirmed in lieu of Res. 514, A-07; BOT Action in response to referred for decision: Res. 927, I-15; Modified: BOT Rep. 09, I-16; Appended: Res. 236, A-17; Reaffirmed in lieu of: Res. 223, A-17)

D-155.987 Price Transparency
1. Our AMA encourages physicians to communicate information about the cost of their professional services to individual patients, taking into consideration the insurance status (e.g., self-pay, in-network insured, out-of-network insured) of the patient or other relevant information where possible. 2. Our AMA advocates that health plans provide plan enrollees or their designees with complete information regarding plan benefits and real time cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect patient out-of-pocket costs. 3. Our AMA will actively engage with health plans, public and private entities, and other stakeholder groups in their efforts to facilitate price and quality transparency for patients and physicians, and help ensure that entities promoting price transparency tools have processes in place to ensure the accuracy and relevance of the information they provide. 4. Our AMA will work with states to support and strengthen the development of all-payer claims databases. 5. Our AMA encourages electronic health records vendors to include features that assist in facilitating price transparency for physicians and patients. 6. Our AMA encourages efforts to educate patients in health economics literacy, including the development of resources that help patients understand the complexities of health care pricing and encourage them to seek information regarding the cost of health care services they receive or anticipate receiving. 7. Our AMA will request that the Centers for Medicare and Medicaid Services expand its Medicare Physician Fee Schedule Look-up Tool to include hospital outpatient payments. (CMS Rep. 4, A-15; Reaffirmed in lieu of: Res. 121, A-16; Reaffirmed in lieu of: Res. 213, I-17; Reaffirmed: BOT Rep. 14, A-18)

H-373.998 Patient Information and Choice
Our AMA supports the following principles: 1. Greater reliance on market forces, with patients empowered with understandable fee/price information and incentives to make prudent choices, and with the medical profession empowered to enforce ethical and clinical standards which continue to place patients' interests first, is clearly a more effective and preferable approach to cost containment than is a government-run, budget-driven, centrally controlled health care system. 2. Individuals should have freedom of choice of physician and/or system of health care delivery. Where the system of care places restrictions on patient choice, such restrictions must be clearly identified to the individual prior to their selection of that system. 3. In order to facilitate cost-conscious, informed market-based decision-making in health care, physicians, hospitals, pharmacies, durable medical equipment suppliers, and other health care providers should be required to make information readily available to consumers on fees/prices charged for frequently provided services, procedures, and products, prior to the provision of such services, procedures, and products. There should be a similar requirement that insurers make available in a standard format to enrollees and prospective enrollees information on the amount of payment provided toward each type of service identified as a covered benefit. 4. Federal and/or state legislation should authorize medical societies to operate programs for the review of patient complaints about fees, services, etc. Such programs would be specifically authorized to arbitrate a fee or portion thereof as appropriate and to mediate voluntary agreements, and could include the input of the state medical society and the AMA Council on Ethical and Judicial Affairs. 5. Physicians are the

patient advocates in the current health system reform debate. Efforts should continue to seek development of a plan that will effectively provide universal access to an affordable and adequate spectrum of health care services, maintain the quality of such services, and preserve patients' freedom to select physicians and/or health plans of their choice. 6. Efforts should continue to vigorously pursue with Congress and the Administration the strengthening of our health care system for the benefit of all patients and physicians by advocating policies that put patients, and the patient/physician relationships, at the forefront. BOT Rep. QQ, I-91; Reaffirmed: BOT Rep. TT, I-92; Reaffirmed: Ref. Cmte. A, A-93; Reaffirmed: BOT Rep. UU, A-93; Reaffirmed: CMS Rep. E, A-93; Reaffirmed: CMS Rep. G, A-93; Reaffirmed: Sub. Res. 701, A-93; Sub. Res. 125, A-93; Reaffirmation A-93; Reaffirmed: BOT Rep. 25, I-93; Reaffirmed: BOT Rep. 40, I-93; Reaffirmed: CMS Rep. 5, I-93; Reaffirmed: CMS Rep. 10, I-93; Reaffirmed: Sub. Res. 107, I-93; Reaffirmed: BOT Rep. 46, A-94; Reaffirmed: Sub. Res. 127, A-94; Reaffirmed: Sub. Res. 132, A-94; Reaffirmed: BOT Rep. 16, I-94; BOT Rep. 36 - I-94; Reaffirmed: CMS Rep. 8, A-95; Reaffirmed: Sub. Res. 109, A-95; Reaffirmed: Sub. Res. 125, A-95; Reaffirmed by Sub. Res. 107, I-95; Reaffirmed: Sub. Res. 109, I-95; Reaffirmed by Rules & Credentials Cmt., A-96; Reaffirmation A-96; Reaffirmation I-96; Reaffirmation A-97; Reaffirmed: Rules and Cred. Cmt., I-97; Reaffirmed: CMS Rep. 3, I-97; Reaffirmation I-98; Reaffirmed: CMS Rep. 9, A-98; Reaffirmation A-99; Reaffirmation A-00; Reaffirmation I-00; Reaffirmation A-04; Consolidated and Renumbered: CMS Rep. 7, I-05; Reaffirmation A-07; Reaffirmation A-08; Reaffirmed: CMS Rep. 4, A-09; Reaffirmed: CMS Rep. 3, I-09; Reaffirmation I-14; Reaffirmed: CMS Rep. 4, A-15; Reaffirmation: A-17; Reaffirmed: Res. 108, A-17)

(21) RESOLUTION 123 - STANDARDIZING COVERAGE OF APPLIED BEHAVIORAL ANALYSIS THERAPY FOR PERSONS WITH AUTISM SPECTRUM DISORDER

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Policies H-90.968 and H-185.963 be reaffirmed in lieu of Resolution 123.

HOD ACTION: Alternate resolution adopted in lieu of Resolution 123.

That our AMA support coverage and reimbursement for evidence-based treatment of Autism Spectrum Disorder including, but not limited to, Applied Behavior Analysis Therapy.

Resolution 123 asks that our AMA support the coverage and reimbursement for Applied Behavioral Analysis for the purpose of treating Autism Spectrum Disorder.

Your Reference Committee heard mixed testimony on Resolution 123. A member of the Council on Medical Service testified that existing policy addresses the intent of Resolution 123 by seeking public and private insurance coverage that reflects the true

cost of health care for individuals with intellectual and developmental disabilities. In addition, the member of the Council on Medical Service testified that the AMA has engaged in advocacy efforts to advance access to care for individuals with developmental disabilities, such as autism. Finally, the Council member explained that AMA policy generally avoids mandating coverage of specific benefits, both to better allow markets to determine benefit packages and to avoid jeopardizing current coverage. Other testimony supported Resolution 123, specifically because it is seeking mandated coverage for a specific treatment.

Your Reference Committee believes that existing policy addresses the intent of Resolution 123. Accordingly, your Reference Committee recommends that Policies H-90.968 and H-185.963 be reaffirmed in lieu of Resolution 123.

H-90.968 Medical Care of Persons with Developmental Disabilities
1. Our AMA encourages: (a) clinicians to learn and appreciate variable presentations of complex functioning profiles in all persons with developmental disabilities; (b) medical schools and graduate medical education programs to acknowledge the benefits of education on how aspects in the social model of disability (e.g. ableism) can impact the physical and mental health of persons with Developmental Disabilities; (c) medical schools and graduate medical education programs to acknowledge the benefits of teaching about the nuances of uneven skill sets, often found in the functioning profiles of persons with developmental disabilities, to improve quality in clinical care; (d) the education of physicians on how to provide and/or advocate for quality, developmentally appropriate medical, social and living supports for patients with developmental disabilities so as to improve health outcomes; (e) medical schools and residency programs to encourage faculty and trainees to appreciate the opportunities for exploring diagnostic and therapeutic challenges while also accruing significant personal rewards when delivering care with professionalism to persons with profound developmental disabilities and multiple comorbid medical conditions in any setting; (f) medical schools and graduate medical education programs to establish and encourage enrollment in elective rotations for medical students and residents at health care facilities specializing in care for the developmentally disabled; and (g) cooperation among physicians, health & human services professionals, and a wide variety of adults with developmental disabilities to implement priorities and quality improvements for the care of persons with developmental disabilities. 2. Our AMA seeks: (a) legislation to increase the funds available for training physicians in the care of individuals with intellectual disabilities/developmentally disabled individuals, and to increase the reimbursement for the health care of these individuals; and (b) insurance industry and government reimbursement that reflects the true cost of health care of individuals with intellectual disabilities/developmentally disabled individuals. 3. Our AMA entreats health care professionals, parents and others participating in decision-making to be guided by the following principles: (a) All people with developmental disabilities, regardless of the degree of their disability, should have access to appropriate and affordable medical and dental care throughout their lives; and (b) An individual's medical condition and welfare must be the basis of any medical decision. Our AMA advocates for the highest quality medical care for persons with profound developmental disabilities; encourages support for health care facilities whose primary mission is to meet the health care

needs of persons with profound developmental disabilities; and informs physicians that when they are presented with an opportunity to care for patients with profound developmental disabilities, that there are resources available to them. 4. Our AMA will continue to work with medical schools and their accrediting/licensing bodies to encourage disability related competencies/objectives in medical school curricula so that medical professionals are able to effectively communicate with patients and colleagues with disabilities, and are able to provide the most clinically competent and compassionate care for patients with disabilities. 5. Our AMA recognizes the importance of managing the health of children and adults with developmental disabilities as a part of overall patient care for the entire community. 6. Our AMA supports efforts to educate physicians on health management of children and adults with developmental disabilities, as well as the consequences of poor health management on mental and physical health for people with developmental disabilities. 7. Our AMA encourages the Liaison Committee on Medical Education, Commission on Osteopathic College Accreditation, and allopathic and osteopathic medical schools to develop and implement curriculum on the care and treatment of people with developmental disabilities. 8. Our AMA encourages the Accreditation Council for Graduate Medical Education and graduate medical education programs to develop and implement curriculum on providing appropriate and comprehensive health care to people with developmental disabilities. 9. Our AMA encourages the Accreditation Council for Continuing Medical Education, specialty boards, and other continuing medical education providers to develop and implement continuing education programs that focus on the care and treatment of people with developmental disabilities. 10. Our AMA will advocate that the Health Resources and Services Administration include persons with intellectual and developmental disabilities (IDD) as a medically underserved population.

H-185.963 Insurance Coverage for Adults with Childhood Diseases

Our AMA: (1) urges public and private third party payers to increase access to health insurance products for adults with congenital and/or childhood diseases that are designed for the unique needs of this population; and

(2) emphasizes that any health insurance product designed for adults with congenital and/or childhood diseases include the availability of specialized treatment options, medical services, medical equipment and pharmaceuticals, as well as the accessibility of an adequate number of physicians specializing in the care of this unique population. (CMS Rep. 2, I-99 Modified and Reaffirmed: CMS Rep. 5, A-09)

(22) RESOLUTION 127 - ELIMINATING THE CMS OBSERVATION STATUS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Policies D-160.932, D-280.988, D-280.989, and H-185.941.be reaffirmed in lieu of Resolution 127.

HOD ACTION: Resolution 127 adopted.

Resolution 127 asks that our AMA request, for the benefit of our patients' financial, physical and mental health, that the Centers for Medicare and Medicaid Services (CMS) terminate the "48 hour observation period" and observation status in total.

Your Reference Committee heard mixed testimony on Resolution 127. A member of the Council on Medical Service testified that AMA policy addresses the intent of Resolution 127 and that the AMA has already taken the advocacy action sought by Resolution 127. The member of the Council on Medical Service also noted that the Council presented a report in 2014 on the Place-of-Service Code for Observation Services that resulted in the reaffirmation and adoption of policy that speaks to the resolution's request. In addition, a member of the Council on Legislation called for reaffirmation, noting that the AMA has already engaged in advocacy efforts that address the intent of Resolution 127. Specifically, the AMA has written to CMS advocating repeal of the "two-midnight" policy several times, including in 2018, 2017, and 2014. Other testimony consistently requested action on this issue.

Your Reference Committee agrees that existing policy addresses the intent of Resolution 127, and supports advocacy efforts to achieve the resolution's objective. The policies recommended for reaffirmation include three directives to take action, and the AMA has, in fact, undertaken significant advocacy action on this issue. As alluded to in testimony by the member of the Council on Legislation, the AMA has repeatedly, over many years, asked CMS resolve this problem. Key advocacy includes:

- In a June 2014 comment letter, the AMA stated, "The AMA has written to CMS numerous times to communicate our serious concerns with CMS' two midnight policy and the rise of observation care, and most recently submitted testimony on this issue before the House Committee on Ways & Means . . . The AMA opposes Medicare's two-midnight policy and believes it should be rescinded in its entirety. Adding to the complexity of the two-midnight policy is the inconsistency between when a hospital stay is considered to be inpatient for purposes of hospital reimbursement versus when a patient is considered an inpatient for purposes of coverage . . . This policy is having very real and negative impact on patient safety. Emergency physicians are reporting patients coming to the emergency department often ask whether they are being admitted as inpatients. If these patients are not given assurances that they will be treated as an inpatient, they leave—even when they clearly require medical attention."
- In a June 2017 comment letter, the AMA stated, "The '2-Midnight' rule has had significant unintended negative consequences that burden Medicare beneficiaries. It remains an artificial construct reflecting a flawed approach that gets in the way of the physician-patient relationship and unnecessarily increases the administrative burden of admitting physicians. . . CMS should rescind the 2-midnight rule in favor of clinical judgement for determining a patient's inpatient/observation status."
- The AMA restated its June 2017 comments in a November 2018 comment letter.

In recognition of existing policy calling for action on this issue and the AMA's longstanding, ongoing zealous advocacy, your Reference Committee believes that an additional directive to take action is unnecessary and would not help the AMA achieve this advocacy goal. Accordingly, your Reference Committee recommends that Policies

D-160.932, D-280.988, D-280.989, and H-185.941 be reaffirmed in lieu of Resolution 127.

D-160.932 Medicare's Two-Midnight Rule
Our AMA will petition the Centers for Medicare & Medicaid Services to repeal the August 19 rules regarding Hospital Inpatient Admission Order and Certification. (Res. 223, I-13 Reaffirmed: CMS Rep. 4, A-14 Reaffirmation A-14)

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

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

H-185.941 Patient Cost-Sharing Requirements for Hospital Inpatient and Observation Services
Our AMA will advocate that patients be subject to the same cost-sharing requirements whether they are admitted to a hospital as an inpatient, or for observation services. (Res. 117, A-12 Reaffirmed: CMS Rep. 4, A-14)

Madam Speaker, this concludes the report of Reference Committee A. I would like to thank William Davison, MD, Gregory Fuller, MD, Russell Libby, MD, Loralie Ma, MD, Kevin Nohner, MD, Laura Shea, MD, and all those who testified before the Committee. I would also like to thank AMA staff: Courtney Perlino, MPP, Julie Marder, JD, and Rebecca Gierhahn, MS.

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