

Informational Reports

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REPORT 1 OF THE BOARD OF TRUSTEES (I-16)
2016 AMA Advocacy Efforts

EXECUTIVE SUMMARY

Policy G-640.005, “AMA Advocacy Analysis,” calls on the Board of Trustees (BOT) to provide a report to the House of Delegates (HOD) at each Interim Meeting highlighting the year’s advocacy activities and should include efforts, successes, challenges, and recommendations/actions to further optimize advocacy efforts. The BOT has prepared the following report to provide an update on 2016 American Medical Association (AMA) advocacy activities.

The AMA had a very productive year once again on the advocacy front led by our Board, Councils, and staff from the Advocacy Group, Strategic Focus Areas, Health and Science, Health Solutions, Enterprise Communications and Marketing, and other AMA units. Our collaborative efforts with the Federation are integral to our successes as well.

Implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), is a major task. The AMA is cognizant of the need to get this right at the practice and policymaking levels, and we are striving to do so. On the insurance merger front, we have had good success in challenging proposed mergers, but the final outcome will be decided in litigation. The opioid crisis continues to ravage our nation, but we are tackling this crisis head on and making progress on some key strategies. We are focusing on other top issues for medicine such as insurer networks, telemedicine, diabetes prevention, and addressing rising pharmaceutical costs. We also continue to call on our nation’s leaders to address Zika before it becomes a more dire situation and more children face lifelong health concerns and a diminished quality of life.

At the time of this writing, we do not know the federal election results, so the political environment in which we will seek to advance our goals in 2017 is to be determined. However, AMPAC is backing candidates who support physician and patient priorities. Our grassroots team will also promote our legislative priorities in 2017 through our various channels. We are also in contact with both presidential campaigns and will engage the presidential transition team to lay out our vision for health care reform on other key issues.

We appreciate the collaboration with the Federation in 2016, and look forward to further work and success in 2017 at the federal and state levels.

Staff note: This report was prepared in September 2016, and may be updated prior to the Interim Meeting based on more recent advocacy developments.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 1-I-16

Subject: 2016 AMA Advocacy Efforts

Presented by: Patrice A. Harris, MD, MA, Chair

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2 report to the House of Delegates (HOD) at each Interim Meeting highlighting the year’s advocacy
3 activities and should include efforts, successes, challenges, and recommendations/actions to further
4 optimize advocacy efforts. The BOT has prepared the following report to provide an update on
5 2016 American Medical Association (AMA) advocacy activities.

6 7 DISCUSSION OF 2016 ADVOCACY EFFORTS

8 9 *MACRA Implementation*

10
11 With the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)
12 behind us, our attention turned immediately to MACRA implementation through the regulatory
13 process where numerous key decisions will be made. MACRA is a complex law, and the proposed
14 regulations to implement it are long and complicated. Compared to the current Medicare physician
15 payment framework, the MACRA law and proposed/final regulations provide significant
16 improvements. Changes to the proposed rule are still needed, and we are advocating forcefully to
17 achieve them in order to reduce regulatory burdens on physicians and to create greater flexibility
18 and choice so physician practices can thrive.

19
20 To help guide our MACRA implementation efforts, the AMA established a MACRA Task Force
21 comprised of national medical specialty societies, state medical associations, the American
22 Osteopathic Association, and the Medical Group Management Association to develop strategic
23 approaches and consistent messaging.^{1,2} We also set up staff workgroups on two key MACRA
24 components – the Merit-based Incentive Payment System (MIPS) and alternative payment models
25 (APMs) to help inform our activities.^{3,4} We have also organized Centers for Medicare & Medicaid
26 Services (CMS) listening sessions with representatives of national medical organizations and state
27 medical associations to improve understanding of MACRA and offer feedback to CMS from across
28 the Federation. Further, we have met regularly with key officials at CMS and the White House on
29 MACRA, and we are keeping Congress apprised of regulatory developments. In addition, the
30 AMA’s 2016 Physician Practice Benchmark Survey will include questions to measure physicians’
31 awareness of MACRA and intended pathways for participation.

32
33 Earlier this year in April, CMS released the first MACRA proposed rule. In response, the AMA
34 filed extensive comments that would lead to a better final rule. (The AMA’s full comments to CMS
35 are available at ama-assn.org/go/medicarepayment.) There are some positive developments in the
36 proposed rule:

- 37
38 • The proposed rule attempts to align three previously disparate and highly burdensome federal
39 reporting programs tied to Medicare payment (Meaningful Use [MU], Physician Quality
40 Reporting System [PQRS], and the Value-based Modifier [VBM]).

- 1 • For the MIPS quality component, the proposed rule reduces the number of quality measures,
2 grants more flexible reporting, and allows for partial credit.
- 3 • In Advancing Care Information (the replacement for the MU program), the proposed rule
4 modifies the 100 percent pass/fail approach and reduces the number of required measures.
- 5 • The proposed rule creates exemptions for physicians whose practices have under \$10,000 in
6 Medicare claims and fewer than 100 patients.
- 7 • It establishes a pathway for physicians to participate in APMs and receive five percent bonus
8 payments from 2019-2024.

9
10 In our comments to the propose rule, we highlighted our top priorities for improvements in the final
11 rule:

- 12
13 • A more realistic start date is needed for reporting requirements under the MIPS program,
14 specifically July 1, 2017 rather than January 1, 2017.
- 15 • Further accommodations are needed for small and rural practices including increasing the low-
16 volume threshold to under \$30,000 in Medicare claims or fewer than 100 patients which AMA
17 estimates will exempt about 29 percent of physicians from MIPS reporting requirements.
- 18 • The four components of the MIPS program are still too complex for physician practices, so
19 further enhancements and streamlining are needed.
- 20 • The APM requirements are too stringent and will lead to too few APM options for physicians,
21 so further flexibility, a more reasonable risk standard, and a more diverse set of models are
22 needed.

23
24 Our comments also discussed other provisions in the proposed rule where refinements are needed.

25
26 In response to advocacy efforts by the AMA and other physician organizations, CMS Acting
27 Administrator Andy Slavitt announced on September 8 in the CMS Blog that the agency was
28 making significant changes to the physician reporting requirements under MACRA for 2017.
29 According to the blog post, the only physicians who risk any negative payment adjustment in 2019
30 will be those who opt not to report at all under MACRA in 2017. Those who do choose to report
31 will have three options with no risk of penalties. Physicians who report for the full year, beginning
32 on January 1, 2017, will be eligible for an unspecified “modest positive payment adjustment.”
33 Under a second option, those who report for part of the calendar year will be eligible for an
34 unspecified “small positive payment adjustment.” Finally, physicians who submit a small amount
35 of data during the year under a “test” option will avoid any negative payment adjustments.
36 Qualified physicians who participate in an Advanced Alternative Payment Model in 2017 will
37 remain eligible for a 5 percent incentive payment in 2019.

38
39 Knowing that this is a complicated and confusing time for physicians as they prepare to adapt their
40 practices to MIPS or seek to participate in an APM, AMA staff from Professional Satisfaction and
41 Practice Sustainability, Advocacy, and Enterprise Communications and Marketing collaborated to
42 develop tools and resources for physicians to assist them with these decisions
43 (ama-assn.org/go/medicarepayment). The Payment Model Evaluator (also available at
44 ama-assn.org/go/medicarepayment) was released in September and is a tool for physicians to assess
45 the impact of MACRA on their practices and obtain implementation resources to maximize their
46 success. The AMA also produced a “[MACRA Checklist](#)” to help physicians prepare for the new
47 payment system. The AMA’s STEPSForward™ program has been recognized by CMS as eligible
48 for Clinical Practice Improvement credit under MACRA. In addition, the AMA is a Support and
49 Alignment Network under the CMS Transforming Clinical Practice Initiative and is providing
50 MACRA education to independent and small practices via Practice Transformation Networks
51 across the country. Additional resources for practices are in development.

1 The final MACRA rule is expected to be released prior to the Interim Meeting. With this report
2 being prepared for the HOD in September, it does not include information on the final rule. Please
3 watch for alerts from the AMA and information on our website. Further information will be
4 available at the Interim Meeting as well assuming that the final rule has been released.

5
6 *Insurer Mergers*

7
8 The Federation and the AMA achieved a major accomplishment when the US Department of
9 Justice (DOJ) and a number of state attorneys general (AGs) filed suit to block the Anthem-Cigna
10 and Aetna-Humana mergers. By working together, the AMA and the state medical associations
11 rang the alarm nationally about the potential negative effects that these mergers could have for
12 patients and physicians. Our collaborative work was instrumental in convincing the DOJ and many
13 state AGs that the proposed mega-mergers should not proceed. The AMA will continue to oppose
14 these mergers aggressively as they enter the litigation phase.

15
16 For over a decade, the AMA has produced research highlighting that health insurance markets in
17 most geographic areas are highly concentrated, and thus provide health insurers with
18 anticompetitive contracting leverage in these markets. This is detrimental to patients and
19 physicians. The 2015 edition of *Competition in Health Insurance: A Comprehensive Study of US*
20 *Markets* was publicized widely in the media and highlighted to policymakers and antitrust
21 regulators such as DOJ and AGs. The AMA also conducted special analyses of states and
22 metropolitan areas, to identify the states and metropolitan areas that would be most negatively
23 affected by one or both of the proposed mergers.

24
25 The AMA showcased this research in testimony before federal and state lawmakers several times.
26 AMA President Andrew W. Gurman, MD, and AMA Trustee Barbara L. McAneny, MD, testified
27 at congressional hearings to discuss our research and express our concerns about health insurance
28 market concentration. We testified and wrote letters to legislators, AGs, and insurance
29 commissioners in several states as well.

30
31 We also regularly convened those state medical associations most likely to be negatively affected
32 by the mergers, to facilitate the exchange of information and strategy, and to ensure that the AMA
33 was providing optimal support to those associations in their merger advocacy. We also had
34 discussions with national groups such as the National Association of Attorneys General (NAAG)
35 and select state insurance regulators. For example, AMA worked very successfully with the
36 Missouri State Medical Association and the California Medical Association to convince their
37 respective insurance regulators to oppose the mergers. AMA filed comments in a number of states,
38 including Florida, Missouri, California, Indiana, Georgia and New York – and worked with a
39 number of others behind the scenes. We brought in economists and legal experts to bolster our
40 case. We worked closely with consumer groups too. The AMA also prepared a member survey for
41 states to gauge the effect of the proposed mergers in their physician communities and passed the
42 results on to the DOJ, as well as state AGs and insurance regulators.

43
44 We expect the health insurers to defend the mergers vigorously, but we will continue to oppose
45 them and continue to build strong coalitions that will challenge them at the federal level, the state
46 level, in the courts, and in public opinion.

47
48 *Opioid Misuse*

49
50 With over 78 deaths per day, the opioid epidemic remains one of the biggest health challenges
51 facing our nation. The AMA is continuing our advocacy and communications efforts through the

1 AMA Task Force to Reduce Opioid Abuse (Task Force), which is comprised of more than 25
2 physician organizations including the AMA, American Osteopathic Association, American Dental
3 Association, national medical specialty societies and state medical associations.⁵ The Task Force
4 has coalesced around pursuing five clear actions:

- 5
- 6 • Increasing physicians' registration and use of effective prescription drug monitoring programs;
 - 7 • Enhancing physicians' education on safe, effective and evidence-based prescribing of opioids;
 - 8 • Reducing the stigma of pain and promoting comprehensive assessment and treatment;
 - 9 • Reducing the stigma of substance use disorder and enhancing access to treatment; and
 - 10 • Supporting overdose prevention efforts by expanding access to naloxone and providing Good Samaritan protections.
- 11

12

13 The severity of the epidemic led to an [open letter](#) from AMA Immediate Past President
14 Steven J. Stack, MD, to physicians on the responsibilities and roles they must play to reduce the
15 opioid epidemic and to make sure physicians are trained in safe prescribing practices.

16

17 At the state level, there were more than 1,000 individual pieces of legislation concerning
18 prescription drug misuse, overdose and death in 2016 – nearly double from 2015. The AMA
19 worked with states individually on pressing bills, and helped more than 10 states secure victories
20 on issues ranging from prescription drug monitoring programs (PDMPs) to increased access to
21 naloxone. We also continued our work with national groups such as the National Governors
22 Association (NGA) which led to a major accomplishment when the AMA and the NGA issued a
23 national joint statement on key recommendations that physician leaders and governors could
24 mutually support. This was the first time that the AMA and NGA had issued such a statement -
25 which included all of the Task Force recommendations. AMA Chair Patrice A. Harris, MD, MA,
26 testified at the NGA's Winter Meeting in support of the recommendations. Furthermore, the Task
27 Force recommendations were emphasized in more than 10 published op-eds and letters to the
28 editor, many of which were joint efforts with state medical associations.

29

30 At the federal level, the AMA expressed support for the recently enacted Comprehensive Addiction
31 and Recovery Act (CARA). The final version of CARA authorizes numerous grant programs
32 focused on prevention of opioid addiction, alternatives to incarceration, increasing the availability
33 of naloxone, supporting PDMPs, promoting medication-assisted therapy and expanding drug take-
34 back programs. The legislation also included other AMA-supported proposals, such as the
35 reauthorization of the National All Schedules Prescription Electronic Reporting Act, which
36 supports state PDMPs, and allows partial fills of Schedule II drugs. While CARA authorizes
37 hundreds of millions of dollars in funding for these programs, Congress must still appropriate the
38 funds in order to fulfill its promise. The AMA will continue to urge Congress to take this critical
39 next step.

40

41 Also at the federal level, a proposed rule issued in July regarding Medicare hospital outpatient and
42 ambulatory surgical center payments in 2017 includes a provision to eliminate the current pain
43 management questions in the Hospital Consumer Assessment of Healthcare Providers and Systems
44 (HCAHPS) patient experience care survey from performance scores beginning in 2018. This was
45 done in response to advocacy by the AMA and others expressing concern that the link between
46 scoring well on the survey and higher facility payments interferes with efforts to curb over-
47 prescribing of opioids. CMS is developing alternative questions for the pain management
48 dimension to address these concerns.

1 *Telemedicine*

2

3 States saw a flurry of activity on telemedicine in 2016, with dozens of laws and regulations
4 proposed to address telemedicine licensure, reimbursement, and practice standards. Many of these
5 laws were based on the AMA “Telemedicine Act,” which addresses these and other issues related
6 to telemedicine. This year, five bills based on this AMA model bill were signed into law.

7

8 While most attention was given to debates over how to establish a patient-physician relationship
9 via telemedicine – in person, using two-way interactive audio-video technology or over the phone –
10 states continued to make gains in passage of coverage parity laws, ensuring that physicians will be
11 compensated for treating their patients via telemedicine. AMA advocacy was instrumental in many
12 of these victories. The AMA is already working towards 2017 legislation with many medical
13 associations from states that lack coverage parity, using the AMA “Telemedicine Act” as a guide.
14 States also continue to advance the “Interstate Medical Licensure Compact,” with 17 states now
15 having enacted it. The Compact facilitates interstate licensure for telemedicine services.

16

17 There has also been significant activity around telemedicine at the federal level. Our AMA
18 continues to advance several major priorities to accelerate the integration of telemedicine into
19 regular clinical practice, including expanding coverage in federal health care programs for
20 telemedicine services, building the evidence base through federal funding for research, and
21 supporting widely supported standards. We are also strongly advocating against efforts by some
22 telecommunications groups to undermine existing state licensure laws, including proposals to
23 create a national licensure scheme or change the site of practice from the state where the patient is
24 located to the state where the physician is located for the purpose of providing telemedicine
25 services to Medicare, the Veterans Health Administration (VA), or DOD TRICARE patients. On
26 the coverage front, the AMA is working with telemedicine stakeholders to draft comments in
27 support of expanded coverage of telehealth services in the Medicare program in response to the
28 proposed 2017 Medicare Physician Fee Schedule, and convening national medical specialty
29 societies to support and urge acceleration of initiatives that grow the evidence base, increase
30 national specialty clinical practice guidelines, and other strategic engagements that ensure
31 physicians have the information and tools to support implementation.

32

33 *Electronic Health Records (EHR) Meaningful Use (MU)*

34

35 In October 2015, CMS announced that the 2015 MU reporting period would be reduced from 365
36 to 90 days. The AMA has consistently urged CMS to implement a shorter reporting period for MU,
37 due to the program’s pass-fail nature and the unforeseeable reporting disruptions that occur due to
38 system failures, the adoption of new vendor products, and other factors beyond a physician’s
39 control. Physicians had until March 15, 2016, to apply for a hardship exemption from three percent
40 MU financial penalties in effect for the 2015 program year. In direct response to AMA advocacy,
41 CMS announced that it would broadly grant hardship exemptions as a result of the delayed
42 publication of the final regulations that announced the policy change, since physicians were left
43 with insufficient time to report that year under the modified program requirements. This inclusive
44 approach to allowing hardship exemptions is a result of the “Patient Access and Medicare
45 Protection Act,” passed just before Congress adjourned for the 2015 holidays, [which directed CMS](#)
46 [to make AMA-supported changes](#) to the previously limited exemption process.

47

48 In July, CMS proposed to implement a 90-day MU reporting period for 2016, as well. The
49 announcement was made in draft regulations pertaining to Medicare hospital outpatient and
50 ambulatory surgical center payment systems for 2017. The AMA has urged CMS to finalize its

1 proposal promptly, to avoid the extraordinary measures that were needed for the 2015 exemptions
2 process due to tardy publication of the regulations.

3
4 Finally, in the MACRA draft regulations, CMS proposed 2017 as the first performance period for
5 MIPS. As it happens, 2017 is also the last year that first-time participants in the MU program may
6 attest to avoid penalties in 2018. Therefore, a new MU participant would be required to participate
7 in both the MU program and the new Advancing Care Information performance category of MIPS
8 in 2017 to avoid any payment adjustment, despite the significant overlap of these two programs.
9 Following AMA advocacy efforts, the proposed rule on Medicare outpatient hospital and
10 ambulatory surgical center payments for 2017 offered a change in this approach, and would allow
11 physicians who have not previously demonstrated MU to apply for a significant hardship
12 exemption from the 2018 payment adjustment and so avoid the duplicative reporting requirements.

13 14 *Insurer Networks/Balance Billing*

15
16 In late 2015, the National Association of Insurance Commissioners (NAIC) finalized its network
17 adequacy model bill, prompting insurance commissioners across the country to push for its
18 adoption by their legislatures. The AMA was heavily involved in the NAIC's process of drafting
19 the model legislation, and as a result of AMA and medicine's advocacy, many important provisions
20 that would improve access to care for patients were included in the final bill. Unfortunately, also
21 included were provisions that threaten access to care and the ability of physicians to negotiate fair
22 contracts with insurers. The AMA offers a detailed, edited version of the NAIC model bill for
23 states to use. As states, such as Connecticut and Maryland, took up the NAIC model this year,
24 medical societies, with assistance from the AMA, worked off of the AMA's version to amend their
25 legislation to better serve patients and physicians and were highly successful in doing so. It is very
26 likely that more states will be proposing versions of the NAIC model next year, and the Federation
27 is already working with insurance commissioners and legislators to propose changes to their
28 version of the legislation.

29
30 When legislators tackle network adequacy issues, balance billing discussions arise as well. In 2016,
31 many states engaged in difficult debates over what should happen when a patient receives a bill
32 from an out-of-network physician while at an in-network facility. With AMA assistance, state
33 medical associations worked hard to accurately frame the issue as a symptom of the larger
34 problems with provider networks and unfair contracting practices. The AMA is working with
35 several coalitions including a work group that we convened with several specialty and state
36 medical associations to find workable solutions.

37 38 *Pharmaceutical Costs*

39
40 In response to a call for action by the HOD at I-15, the AMA convened a Task Force on
41 Pharmaceutical Costs,⁶ chaired by AMA Chair-Elect Gerald E. Harmon, MD, to develop principles
42 to guide grassroots efforts aimed at addressing pharmaceutical costs and improving patient access.
43 Board of Trustees Report 10-I-16, "AMA Initiatives on Pharmaceutical Costs," contains a full
44 update on this issue, but to provide a snapshot, the Task Force recommended that increasing
45 transparency among pharmaceutical companies, health plans and pharmacy benefit managers
46 (PBMs) should be the focus of Phase I of the HOD-directed grassroots campaign. The AMA
47 launched and is promoting an online petition that calls on Congress to demand that these
48 companies introduce a basic level of transparency to the general public. The petition is being
49 featured on cause-oriented websites frequented by online activists on both sides of the political
50 spectrum (e.g., standunited.org), as well as specifically promoted to the AMA's Patient's Action
51 Network. This fall, a campaign-specific microsite focused on drug pricing transparency will be

1 launched in order to build on the initial interest generated by the online petition and related
2 promotional activities. Following the November elections, additional public opinion research and
3 message testing will be conducted to help provide further guidance on how to best advocate on this
4 topic.

5
6 *Zika Prevention Funding*

7
8 On May 26, 2016, the AMA wrote the bipartisan leadership of Congress, urging “immediate action
9 to make available the necessary resources to prepare our nation to address the growing threat of the
10 Zika virus.” The AMA has also joined the efforts of a broad coalition of organizations, including
11 the March of Dimes, the American Congress of Obstetricians and Gynecologists, and the American
12 Academy of Pediatrics in continuing to advocate for congressional action. Though Congress
13 recessed for the summer without taking final action on funding, AMA continues to press for a
14 resolution to the funding dispute as soon as possible. The AMA is also working with the coalition
15 on state strategies to combat the spread of Zika.

16
17 *Proposed Medicare Fee Schedule*

18
19 The annual proposed rule on the Medicare physician payment schedule, issued in July, included
20 both favorable and unfavorable policy proposals. Policies in the proposed rule that the AMA will
21 support in its comments include:

- 22
23 • Following up on an announcement earlier this year, the draft regulation proposes to expand the
24 duration/scope of the Diabetes Prevention Program (DPP) model. Under the new program, to
25 be known as the Medicare Diabetes Prevention Program (MDPP), providers could deliver
26 services either in-person or via remote technologies.
- 27 • Several policy updates were made for primary care services, including improved payments for
28 chronic care management services and a separate payment for behavioral health integration
29 models.
- 30 • Despite statements made earlier in the year by former CMS officials, the agency did not
31 propose to revise existing policies and will continue to exclude industry support for
32 independent continuing medical education in the Open Payments Program (Sunshine Act)
33 reporting data base.

34
35 Other policies outlined in the proposed rule are more problematic:

- 36
37 • As part of a data collection effort on the frequency of and inputs involved in providing global
38 surgical services, CMS is proposing to require comprehensive claims-based reporting on the
39 number and level of pre- and post-operative services furnished during 10- and 90-day global
40 periods. This would require physicians to report a set of time-based G-codes (in 10-minute
41 increments) that distinguish between the setting of care and whether the services are provided
42 by a physician or their clinical staff. The extraordinary administrative burden would be
43 imposed during the first MACRA reporting year – on January 1, 2017 – when physicians are
44 already adapting to broad regulatory changes. The AMA is working with a coalition of
45 specialty organizations to stop this proposal and replace it with a data collection effort more in
46 line with congressional intent.
- 47 • CMS is proposing an add-on code that could be billed with an evaluation and management
48 service for physicians treating patients with mobility-related impairments. Payments for this
49 add-on code would be funded through an across-the-board cut in Medicare payment rates in
50 2017. The AMA is exploring alternative approaches to recommend for improving access to
51 care for these patients.

1 *Tobacco Regulation*

2

3 In August, the US Food and Drug Administration (FDA) released its [final rule](#) regulating
4 e-cigarettes, cigars, hookah and other previously unregulated tobacco products. The new rules are
5 sweeping in scope, and for the first time, extend federal regulatory authority to e-cigarettes,
6 banning their sale to minors under the age of 18 and requiring health warnings.

7

8 Also required under the rules:

9

- 10 • Adults under the age of 26 must show a photo identification to buy these tobacco products.
11 • Producers must register with the FDA and provide a detailed accounting of the ingredients in
12 their products and their manufacturing processes.
13 • Manufacturers are prohibited from making unproven health claims.
14 • Manufacturers must apply to the FDA for permission to sell their products.

15

16 As recommended by the AMA and other public health stakeholders, the FDA extended the rules to
17 all cigars, rejecting proposals to exempt so-called “premium cigars.” The AMA has long called for
18 e-cigarettes to be subject to the same regulations and oversight that the FDA applies to tobacco and
19 nicotine products, and supports the final rule as an important step in protecting the public’s health,
20 especially that of minors. However, the AMA believes further regulation is necessary with regard
21 to marketing e-cigarettes and banning flavored e-cigarettes, which are particularly enticing to
22 minors.

23

24 The AMA is also assisting state medical associations with efforts to raise the minimum age for
25 purchasing tobacco and electronic smoking devices. For example, with AMA support, California
26 raised the age to purchase tobacco products to 21 this year, making it the second state to do so.

27

28 *Medical Liability Reform*

29

30 The AMA and the Federation continue to promote and defend medical liability reform (MLR).
31 Most of the activity is occurring at the state level in recent years. In 2016, states considered bills
32 that promoted a variety of reforms, including expert witness guidelines, affidavit of merit
33 requirements, collateral source reform and bills that established structures such as pretrial screening
34 panels or health court systems. Most of these bills did not progress to enactment. A handful of
35 states had to engage in defensive efforts as they faced attempts to raise caps on non-economic
36 damages. Most efforts to defeat cap bills were successful, while at the eleventh hour, the Indiana
37 legislature passed a long-pending bill to raise the state’s 18-year old cap from \$1.25 million to
38 \$1.65 million in 2017 and \$1.8 million in 2019.

39

40 *Team-based Care/Scope of Practice*

41

42 In 2016, the AMA continued to promote physician-led teams at the state level and to fight
43 inappropriate scope of practice legislation. State legislatures considered over 500 bills seeking to
44 eliminate team-based care models of health care delivery and/or expand the scope of practice of
45 non-physician health care professionals. The AMA expects this high level of legislative activity to
46 continue in 2017.

47

48 Though tough fights in all cases, most bills that threatened passage were defeated with the support
49 of the AMA, in close coordination with state and specialty medical associations. For example, bills
50 pursuing independent practice of advanced practice nurses were defeated in 12 states. In two of
51 those states – Arizona and Ohio – grants from the Scope of Practice Partnership (SOPP) played a

1 key role in supporting efforts to defeat independent practice bills from nurse anesthetists and nurse
2 practitioners, respectively. AMA advocacy and SOPP support also helped to defeat bills to allow
3 psychologists to prescribe psychotropic medication. To date, the SOPP has granted nearly \$1.4
4 million to state and specialty medical societies in support of scope of practice, truth in advertising,
5 and physician-led team advocacy efforts.

6 7 *Nurse Practitioners in the Veterans Health Administration*

8
9 The Veterans Health Administration (VA) published a [proposed rule](#) in May that would give full
10 practice authority to four categories of advanced practice registered nurses (APRN): certified nurse
11 practitioner, certified registered nurse anesthetist, clinical nurse specialist, and certified nurse-
12 midwife. The proposal would allow APRNs working within the scope of VA employment to
13 provide services without the clinical oversight of a physician, regardless of state or local law
14 restrictions on that authority. Efforts at the VA to permit independent nursing practice go back
15 several years but gained momentum when significant staffing shortages and long patient wait times
16 were uncovered in 2014.

17
18 In addition to meetings of AMA Trustees with VA officials on this subject, the AMA submitted
19 comments opposing the proposed rule and urged members of the Federation to do the same. The
20 AMA submitted a [sign-on letter](#) on behalf of 98 specialty and state medical societies urging the VA
21 not to move forward with the proposal.

22 23 *Prior Authorization*

24
25 The AMA is conducting a major research project on prior authorization (see “New Advocacy
26 Research” section that follows) and has formed a work group with Federation groups and other
27 stakeholders to address this issue. In 2016, the AMA worked with several states to propose new
28 legislative ideas on this problematic issue. Delaware enacted legislation based on the AMA model
29 prior authorization bill that requires reporting of prior authorization statistics by insurers or benefit
30 managers to a state database. The data is likely to prove invaluable in studying the impact and
31 utility of prior authorization. Additionally, Ohio and Delaware were able to include AMA model
32 provisions in their new laws that make prior authorizations valid for a year and prevent retroactive
33 denials. They were also both able to include a transition to electronic prior authorization (ePA) to
34 automate the prior authorization process, a major priority of the AMA.

35 36 2016 GRASSROOTS/GRASSTOPS ACTIVITIES

37
38 In order to provide both patient and physician advocates with the best tools and resources, the
39 AMA Patient’s Action Network and Physicians’ Grassroots Network recently made changes to
40 their online advocacy platforms. On the patient side, this included: an updated website design
41 for [PatientsActionNetwork.org](#); a new call to action on freeing up regulations that affect electronic
42 health records and interfere with the patient-physician relationship; even more resources to help
43 enhance advocacy efforts; an interactive “share your story” feature; and, stronger social media tools
44 to make it easier to connect with fellow advocates. For physicians, changes focused on broadening
45 the scope of [BreaktheRedTape.org](#) to include new issues important to medicine such as the opioid
46 misuse crisis, MACRA, telemedicine, and drug pricing transparency. New action-taking tools and
47 online resources will be available to physicians as well, enabling them to communicate with
48 lawmakers on these important issues through social media channels and new, interactive video-
49 sharing technologies.

1 In conjunction with the Medical Student Advocacy and Region Conference held earlier this year,
2 the AMA has also launched an updated version of SaveGME.org. The updates include new
3 resources and content, including video submissions from medical students and a call to action on
4 the Public Service Loan Forgiveness Program. In addition, new videos and social media outreach
5 expected to be unveiled in the fall will be focused on expanding the SaveGME campaign's mission
6 to focus on raising awareness with the general public on the urgent need to preserve adequate
7 funding for graduate medical education.

8 9 2016 AMPAC ACTIVITIES

10
11 AMPAC has once again worked closely with its state medical association PAC partners this
12 election cycle on contribution support decisions for candidates running for the US House of
13 Representatives and Senate. A report summarizing AMPAC activities will be distributed at the
14 Interim Meeting in Orlando.

15 16 FEATURED ADVOCACY RESOURCES

17
18 The AMA has also produced new resources to assist physicians:

- 19
20 • [Guide to Physician-focused Alternative Payment Models](#): The AMA worked with Harold
21 Miller at the Center for Healthcare Quality and Payment Reform, a member of the newly
22 appointed Physician-Focused Payment Models Technical Advisory Committee to the federal
23 government, to develop a guide to help physicians understand the various types of APMs and
24 how their practice may be able to participate in a new model.
- 25 • [HIPAA podcast](#): The AMA and the Healthcare Information and Management Systems Society
26 (HIMSS) produced this podcast to answer questions about providing patients access to their
27 health information, as required by the Health Insurance Portability and Accountability Act
28 (HIPAA).
- 29 • [AMA Health Workforce Mapper](#): The AMA launched an update of the AMA Health
30 Workforce Mapper, an interactive online resource that illustrates the distribution of physicians
31 and non-physician clinicians by specialty, state, county, or metropolitan areas. The AMA
32 Health Workforce Mapper provides a useful visual tool to demonstrate to law- or policymakers
33 the geographic distribution of the health care workforce in a given state or nationally, to assist
34 them in making appropriate, evidence-based decisions. The updated Health Workforce Mapper
35 now integrates CDC data on morbidity, mortality, health care access and quality, health
36 behavior demographics and social environments, further helping to ensure that patients have
37 access to the care they need.
- 38 • [Workers' Compensation and Auto Injury Toolkit](#): The AMA recently updated its Workers'
39 Compensation and Auto Injury Toolkit. This resource offers a primer on property and casualty
40 billing, as well as provides valuable practice tips for transitioning from manual to electronic
41 processes for these business lines.

42 43 NEW ADVOCACY RESEARCH

44
45 The AMA has also produced the following studies to assist in our efforts:

- 46
47 • [Policy Research Perspective - Payment and Delivery in 2014: The Prevalence of New Models
48 Reported by Physicians](#): This publication presents a national view of physician participation in
49 new payment and delivery models by specialty, practice type and practice ownership. Based on
50 the 2014 Physician Practice Benchmark Survey, it concludes that although the majority (59.0
51 percent) of physicians worked in practices that received revenue from at least one alternative

1 payment model, fee-for-service payment was still the dominant payment method used by
2 insurers to pay physician practices. An average of 71.9 percent of practice revenue came from
3 fee for service. A 2016 edition of this study is forthcoming in 2017.

- 4 • [Competition in Health Insurance: A Comprehensive Study of US Markets](#): In this report, the
5 AMA produces the largest, most complete picture of competition in the commercial health
6 insurance markets across the US. It is a valuable resource for physicians, policymakers,
7 regulators, researchers, and patients. It has been a vital component of our campaign to halt the
8 proposed insurance mergers.
- 9 • [Prior Authorization](#): The AMA is partnering with the University of Southern California
10 Schaeffer Center for Health Policy & Economics in an ambitious research project focused on
11 prior authorization. Through rigorous analysis of claims and clinical data, this study will assess
12 the impact of prior authorization on resource utilization, costs (both for a particular service and
13 overall health care expenditures), and patient outcomes. While health plans endorse prior
14 authorization as a mechanism to control costs, the more holistic analysis proposed for this
15 study may show an overall lack of value for the health care system. Results from the study will
16 be targeted for publication in a peer-reviewed journal in 2017 and will provide valuable
17 support to the AMA's evidence-based advocacy on this issue.
- 18 • [Narrow Network Regulation](#): Recent research conducted by the Georgetown University Health
19 Policy Institute (Georgetown), commissioned by the AMA, presents important findings
20 regarding the regulation of narrow networks, specifically with regard to consideration of
21 quality as a component of regulation. As highlighted by Georgetown researchers, state
22 regulators generally do not define or regulate "narrow networks" or "tiered networks" any
23 differently than standard networks. Additionally, when the Georgetown researchers drilled
24 down on the issue of quality and asked state regulators and other stakeholders whether state
25 provider network rules should incorporate the concept of quality, especially when assembling
26 narrow networks, they found little to no focus on quality in network design, even in the
27 narrowest of networks. At the time of this writing, the research, along with a supplemental
28 AMA discussion document, is set to be released in September to complement and enhance the
29 AMA's state advocacy on network adequacy and physician profiling issues.
- 30 • [National survey: Physician perceptions and practices on opioid prescribing, education, barriers
31 to care, naloxone](#): The AMA released the findings of a national physician survey that showed
32 strong support for key policies and recommendations to help reverse the nation's opioid
33 epidemic, including ways to improve prescription drug monitoring programs, enhance
34 physician education as well as remove barriers to care. The survey found, among other things,
35 that PDMPs need improvement to integrate with electronic health records, provide real-time
36 data and other key features that would make them even more useful. The survey also found that
37 a majority of respondents have taken continuing medical education (CME) on safe opioid
38 prescribing and strong support for increasing access to naloxone.

39 40 CONCLUSION

41
42 As shown by this report, the AMA continues to advocate for physicians and patients on numerous,
43 vital health care issues, and we continue to have a positive impact. In 2017, our advocacy efforts
44 will focus on MACRA implementation (with a particular emphasis on assisting small practices);
45 the opioid crisis; health insurer mergers; pharmaceutical pricing; health insurer networks; public
46 health topics; and other issues that arise. We are gearing up for a new Administration and Congress
47 and will be ready to move forward once our new federal and state officials assume office. We
48 appreciate the collaboration with the Federation in 2016, and look forward to further work and
49 success in 2017 at the federal and state levels.

REFERENCES

- ¹ National Medical Specialty Societies – American Academy of Family Physicians, American Academy of Ophthalmology, American Association of Neurological Surgeons, American Association of Orthopaedic Surgeons, American College of Cardiology, American College of Emergency Physicians, American College of Physicians, American College of Surgeons, American Psychiatric Association, and American Society of Clinical Oncology.
- ² State Medical Associations – Illinois State Medical Society, Massachusetts Medical Society, North Carolina Medical Society, Ohio State Medical Association, Texas Medical Association, Washington State Medical Association, and Wisconsin Medical Society.
- ³ MIPS workgroup – American Association for Clinical Endocrinology, American Association of Neurological Surgeons, American College of Cardiology, American College of Radiology, American Osteopathic Association, AMDA (The Society for Post-Acute and Long-Term Care Medicine), American Society of Cataract and Refractive Surgery, American Society of Gastrointestinal Endoscopy, Illinois State Medical Society, Maine Medical Association, Medical Group Management Association, North Carolina Medical Society, Society of Gynecologic Oncology, and Texas Medical Association.
- ⁴ APM workgroup – American Academy of Otolaryngology-Head and Neck Surgery, American College of Emergency Physicians, American College of Physicians, American College of Surgeons, American Psychiatric Association, American Gastroenterological Society, American Society of Clinical Oncology, American Society for Therapeutic Radiology and Oncology, American Urological Association, American Uro-gynecologic Society, California Medical Association, Massachusetts Medical Society, Society of Gynecologic Oncology, Society of Thoracic Surgeons, Washington State Medical Association, and Wisconsin Medical Society.
- ⁵ AMA Task Force to Reduce Opioid Abuse (Task Force) – American Academy of Addiction Psychiatry, American Academy of Family Physicians, American Academy of Hospice and Palliative Medicine, American Academy of Orthopaedic Surgeons, American Academy of Neurology, American Academy of Pain Medicine, American Academy of Pediatrics, American Academy of Physical Medicine and Rehabilitation, American Association of Neurological Surgeons, American College of Emergency Physicians, American College of Occupational and Environmental Medicine, American College of Physicians, American College of Rheumatology, American Congress of Obstetricians and Gynecologists, American Dental Association, American Medical Association, American Osteopathic Association, American Psychiatric Association, American Society of Addiction Medicine, American Society of Anesthesiologists, Arkansas Medical Society, Massachusetts Medical Society, Medical Society of the State of New York, New Mexico Medical Society, Ohio State Medical Association, Oregon Medical Association, and Utah Medical Association.
- ⁶ AMA Task Force on Pharmaceutical Costs – AMA Council on Legislation, AMA Council on Medical Service, AMA Council on Science and Public Health, Medical Association of the State of Alabama, California Medical Association, Massachusetts Medical Society, Minnesota Medical Association, American Academy of Dermatology, American Academy of Pediatrics, American College of Cardiology, American College of Physicians, and American Society of Clinical Oncology.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 4-I-16

Subject: Redefining the AMA's Position on the ACA and Health Care Reform - Update

Presented by: Patrice A. Harris, MD, MA, Chair

1 At the 2013 Annual Meeting of the House of Delegates (HOD), the HOD adopted Policy
2 D-165.938, "Redefining AMA's Position on ACA and Healthcare Reform," which called on our
3 American Medical Association (AMA) to "develop a policy statement clearly outlining this
4 organization's policies" on a number of specific issues related to the Affordable Care Act (ACA)
5 and health care reform. The adopted policy went on to call for our AMA to report back at each
6 meeting of the HOD. Board of Trustees (BOT) Report 6-I-13 accomplished the original intent of
7 the policy. This report serves as an update on the issues and related developments occurring since
8 the most recent meeting of the HOD.

9 10 REPEAL AND APPROPRIATE REPLACEMENT OF THE SGR

11
12 As previously reported, the repeal of the Sustainable Growth Rate (SGR) was accomplished with
13 the enactment of the "Medicare Access and CHIP Reauthorization Act of 2015" (MACRA) on
14 April 16, 2015.

15
16 On April 28, 2016, the Centers for Medicare & Medicaid Services (CMS) released proposed
17 implementing regulations [Merit-Based Incentive Payment System (MIPS) and Alternative
18 Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-
19 Focused Payment Models; Proposed Rule (CMS-5517-P)]. Following consultation with state and
20 national medical specialty societies, the AMA responded with extensive comments¹ on June 27,
21 2016. Our AMA and 118 state and national medical specialty societies sent a separate comment
22 letter² on June 24, 2016 outlining areas of broad agreement among physician organizations.

23 24 PAY-FOR-PERFORMANCE

25
26 Inherent in the implementation of MACRA is the opportunity to reshape current pay-for-
27 performance programs. As stated in AMA comments to CMS, "the intent of MACRA was not to
28 merely move the current incentive programs into MIPS but to improve and simplify these programs
29 into a single more unified approach." AMA comments on the proposed regulations are lengthy and
30 may be accessed at: ama-assn.org/go/medicarepayment. In the most general terms, our AMA has
31 called on CMS to create a transition reporting period so that physicians may prepare for a
32 successful implementation, provide additional flexibility for solo and small group practices, and
33 provide more timely and actionable feedback in a usable and clear format. More specifically, our
34 AMA made 13 high-level recommendations:

- 35
36
- Establish a transitional period to allow for sufficient time to prepare physicians to have a
37 successful launch of MACRA.
 - Provide more flexibility for solo physicians and small group practices, including raising the
38 low volume threshold.
- 39

- 1 • Provide physicians with more timely and actionable feedback in a more usable and clear
2 format.
- 3 • Align the different components of MIPS so that it operates as a single program rather than four
4 separate parts, such as creating a common definition for small practices.
- 5 • Simplify reporting burdens and improve chances of success by creating more opportunities for
6 partial credit and fewer required measures within MIPS.
- 7 • Reduce the thresholds for reporting on quality measures.
- 8 • Reward reporting of outcome or cross-cutting measures under a bonus point structure rather
9 than a requirement in order to achieve the maximum quality score.
- 10 • Improve risk adjustment and attribution methods before moving forward with the resource use
11 category.
- 12 • Replace current cost measures that were developed for hospital-level measurement and refine
13 and test new episode measures prior to widespread adoption.
- 14 • Permit proposals for more relevant measures, rather than keeping the current MU Stage 3
15 requirements.
- 16 • Remove the pass-fail component of the Advancing Care Information (ACI) score.
- 17 • Reduce the number of required Clinical Practice Improvement Activities (CPIAs) and allow
18 more activities to count as “high-weighted.”
- 19 • Simplify and lower financial risk standards for Advanced APMs.

20
21 Though final regulations are not expected until autumn, our AMA continues to encourage all
22 physicians to prepare for the transition. Numerous resources have been made available on the
23 AMA MACRA webpage (ama-assn.org/go/medicarepayment), including an action kit
24 (download.ama-assn.org/resources/doc/washington/16-0384-advocacy-macra-action-kit.pdf)
25 detailing steps that practices should take now as well as explanatory material on the two options for
26 participating, the Merit-based Incentive Payment System and Alternative Payment Models.
27 Additionally, the AMA’s STEPSForward™ practice improvement initiatives provide a step-by-step
28 process to help prepare practices for value-based care.

29 30 REPEAL AND REPLACE THE INDEPENDENT PAYMENT ADVISORY BOARD (IPAB)

31
32 As noted in BOT Report 7-A-16, the House of Representatives has passed H.R. 1190, the
33 “Protecting Seniors’ Access to Medicare Act of 2015,” repealing the IPAB. While the AMA
34 supported the passage of the House bill, the funding provisions, specifically cuts to the ACA
35 Prevention and Public Health Fund, are contrary to AMA policy. Our AMA continues to explore
36 possible pathways for consideration of the Senate-introduced bill though no action has been
37 scheduled at this time.

38 39 SUPPORT FOR MEDICAL SAVINGS ACCOUNTS, FLEXIBLE SPENDING ACCOUNTS, 40 AND THE MEDICARE PATIENT EMPOWERMENT ACT

41
42 H.R. 1270, the “Restoring Access to Medication Act of 2015” was passed by the House on July 6,
43 2016 by a vote of 243-164. The legislation would repeal a provision of the Affordable Care Act
44 that prohibited the use of Flexible Spending Accounts for the purchase of over the counter
45 medications without a prescription and increase allowable contributions to Health Savings
46 Accounts. The White House has announced that the President would veto the measure if it were
47 presented for signature. In releasing the White House Statement of Administration Policy, the
48 Office of Management and Budget expressed opposition to provisions in the legislation that would
49 “provide additional tax breaks that disproportionately benefit those with higher incomes” and
50 “increase taxes paid by low- and middle-income families.” This objection refers to the funding
51 provision of the House-passed bill that would pay for increases in HSA contributions by increasing

1 subsidy recapture provisions for those who receive subsidies for the purchase of ACA coverage.
2 The Senate has not scheduled action on the bill.

3
4 As previously reported, the “Medicare Patient Empowerment Act” has been reintroduced in the
5 current Congress by Rep. Tom Price, MD, (R-GA) and Sen. Lisa Murkowski (R-AK). The House
6 version, H.R. 1650, currently has 30 cosponsors while the Senate bill, S. 1849, has six cosponsors.
7 Neither bill has been scheduled for consideration at this time.

8 9 STEPS TO LOWER HEALTH CARE COSTS

10
11 The AMA continues to seek opportunities to advance policies that will lower health care costs.
12 Central to these efforts is the AMA’s work on Improving Health Outcomes. One key component of
13 the work of our AMA on improving health outcomes is the expansion of coverage for the Diabetes
14 Prevention Program (DPP). As part of the CY 2017 Medicare Physician Fee Schedule Proposed
15 Rule published on July 15, 2016, CMS proposes to expand the duration and scope of the DPP
16 model test, and refer to the new program as the Medicare Diabetes Prevention Program (MDPP).
17 The proposed rule provides a basic framework for the MDPP, and CMS notes that if finalized, they
18 will engage in additional rulemaking within the next year to establish specific MDPP requirements.
19 This development represents a significant step forward in efforts to expand coverage for DPP.

20 21 REPEAL NON-PHYSICIAN PROVIDER NON-DISCRIMINATION PROVISIONS OF THE 22 ACA

23
24 Legislation repealing the non-physician provider non-discrimination provisions of the ACA has not
25 been introduced in the current Congress to date.

26 27 CONCLUSION

28
29 AMA Policy D-165.938 calls for updates at each meeting of the HOD on a number of specific
30 policies related to the ACA. Our AMA continues to pursue these issues. Other key advocacy issues
31 will continue to be addressed in the annual Advocacy report at each Interim Meeting of the House.

REFERENCES

¹ <https://download.ama-assn.org/resources/doc/washington/ama-macra-comments-27june2016.pdf>

² <https://download.ama-assn.org/resources/doc/washington/macra-state-speciality-sign-on-letter.pdf>

REPORT OF THE BOARD OF TRUSTEES

B of T Report 10-I-16

Subject: AMA Initiatives on Pharmaceutical Costs

Presented by: Patrice A. Harris, MD, MA, Chair

1 Physician concerns about the impact of the current and projected growth in pharmaceutical spending
2 and pricing on patient access, affordability and adherence to prescription drugs resulted in the
3 adoption of new American Medical Association (AMA) policy and directives at the 2015 Interim
4 Meeting. Notably, Council on Medical Service Report 2-I-15, “Pharmaceutical Costs,” established
5 policy that encourages drug price and cost transparency among pharmaceutical companies, pharmacy
6 benefit managers and health insurance companies; supports legislation to require generic drug
7 manufacturers to pay an additional rebate to state Medicaid programs if the price of generic drug rises
8 faster than inflation; encourages Federal Trade Commission actions to limit anticompetitive behavior
9 by pharmaceutical companies to reduce competition from generic manufacturers through manipulation
10 of patent protections and abuse of regulatory exclusivity incentives; and supports legislation to shorten
11 the exclusivity period for biologics (Policy H-110.987). In addition, the report was amended to include
12 the following two directives:

- 13
14 • That our AMA will convene a task force of appropriate AMA Councils, state medical societies
15 and national medical specialty societies to develop principles to guide advocacy and grassroots
16 efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to
17 medically necessary prescription drug regimens.
- 18
19 • That our AMA generate an advocacy campaign to engage physicians and patients in local and
20 national advocacy initiatives that bring attention to the rising price of prescription drugs and help
21 to put forward solutions to make prescription drugs more affordable for all patients, and report
22 back to the House of Delegates regarding the progress of the drug pricing advocacy campaign at
23 the 2016 Interim Meeting.

24
25 The following report, which is presented for the information of the House of Delegates (HOD),
26 summarizes the work of the Task Force on Pharmaceutical Costs and describes the first phase of the
27 AMA’s grassroots campaign on drug pricing.

28 29 TASK FORCE ON PHARMACEUTICAL COSTS

30
31 The AMA Board of Trustees appointed a 13-member task force in December 2015, consisting of
32 representatives of three AMA councils (Council on Legislation, Council on Medical Service, and
33 Council on Science and Public Health), four state medical associations (Medical Association of the
34 State of Alabama, California Medical Association, Massachusetts Medical Society, and Minnesota
35 Medical Association) and five national medical specialty societies (American Academy of
36 Dermatology, American Academy of Pediatrics, American College of Cardiology, American College
37 of Physicians, and American Society of Clinical Oncology). Current AMA Board of Trustees Chair-
38 Elect Gerald E. Harmon, MD, was appointed chair of the task force.

1 Per the directive of the HOD, the charge of the task force was focused: to review current AMA policy
2 and develop principles to help guide AMA advocacy and grassroots efforts aimed at addressing
3 pharmaceutical costs and improving patient access and adherence to medically necessary prescription
4 drugs. In particular, the task force was asked to offer recommendations on which combination of
5 existing AMA policies should be pursued to advance a cohesive vision in order to successfully
6 influence public policy.

7
8 The task force was asked to complete its work within six months—prior to the 2016 Annual Meeting.
9 In January 2016, the task force held a face-to-face meeting in Washington, DC. At the meeting, the
10 task force reviewed AMA policy on pharmaceutical costs and pricing; reviewed a draft document on
11 possible metrics for evaluating AMA policy for inclusion in an AMA grassroots campaign; received a
12 briefing on the 2016 political landscape and the impact of the presidential and congressional elections
13 on this issue; heard from task force members on specific campaigns/advocacy efforts that their
14 respective organizations have undertaken; and held an initial discussion on potential issues and issue
15 combinations to feature in an AMA grassroots campaign.

16
17 The task force held follow-up conference calls in March, April and May of 2016, during which it
18 reviewed and discussed documents that described advocacy campaign opportunities on the issue of
19 transparency (for pharmaceutical companies, health plans and pharmacy benefit managers [PBMs]);
20 explained Medicare drug price negotiations and compared how drug prices are currently determined
21 by Medicare Part D and the Veterans Administration; summarized current federal legislation to allow
22 such negotiation; and presented cost savings estimates from Congressional Budget Office, the Centers
23 for Medicare & Medicaid Services' Office of the Actuary, and others.

24
25 In summary, the task force reached consensus on the following:

- 26
- 27 • Agreement on the use of a set of metrics for evaluating current AMA policy for inclusion in an
28 AMA grassroots campaign (see appendix).
 - 29
 - 30 • Agreement that neither drug importation nor a ban on direct-to-consumer advertising should be
31 pursued as part of the grassroots campaign at this time.
 - 32
 - 33 • Agreement that increasing transparency among pharmaceutical companies, health plans and PBMs
34 should be the focus of Phase I of the grassroots campaign (remainder of 2016).
 - 35
 - 36 • Agreement that the specifics of Phase II of the grassroots campaign (2017) should be determined
37 after the 2016 presidential and congressional elections and after any additional policy is
38 established by the House of Delegates following completion of the planned I-16 report by the
39 Council on Medical Service (e.g., value-based drug pricing and/or Medicare drug price
40 negotiation). However, strong consideration should be given to including Medicare drug price
41 negotiation in Phase II of the campaign.
 - 42

43 AMA GRASSROOTS CAMPAIGN AND FURTHER POLICY DEVELOPMENT

44

45 To raise initial awareness regarding the need for pharmaceutical companies, health plans and PBMs to
46 inject greater transparency in their process for determining drug prices, the AMA launched and
47 promoted an online petition during the summer of 2016, calling on Congress to demand these
48 companies introduce a basic level of transparency to the general public. The petition is currently
49 featured on cause-oriented websites frequented by online activists on both sides of the political
50 spectrum (e.g., standunited.org), and is also being specifically promoted to the AMA's Patient Action

1 Network, along with other information including articles and other policy pieces that discuss the issue,
2 through the network's website, email newsletters, and social media channels.

3
4 A specific campaign microsite, focused on drug pricing transparency, was scheduled to be launched in
5 the fall of 2016 in order to build on the initial interest generated by the online petition and related
6 promotional activities. The site will have a serious and generally hard-hitting tone in order to reinforce
7 the importance of the issue and the need for people to get involved and take action. Although the
8 primary audience is the general public and anyone concerned about the rising cost of drugs, specific
9 content and resources for physicians to impact the debate will be made available as well. As the online
10 hub for the campaign, the website will act primarily as a platform for activists to make their voices
11 heard with members of Congress and potentially state legislators through email and social media
12 communications. Additional key components of the site will include: lead/feature video summarizing
13 the campaign's central arguments through flash animation or a still photo/headline carousel; a "get the
14 facts" section housing one-pagers and links to more in-depth policy analysis and interactive
15 infographics that showcase the campaign's arguments on cost, pricing, and the relationship between
16 health insurers and PBMs; a news section with links to stories about what is happening on the issue at
17 the state and national level; a "share-your-story" section that will prompt both patient and physician
18 visitors to the site to share their experiences in grappling with the high-cost of prescription drugs; and
19 an "action center" that in addition to the basic advocacy tools enabling users to email, tweet and post
20 Facebook messages to their lawmakers, will house the campaign's main petition, as well as a tool that
21 will help them in submitting letters-to-the-editor on this issue in publications in their local
22 communities.

23
24 Following the November elections, additional public opinion research and message testing will be
25 conducted. The extensive polling conducted in California related to its ballot initiative on drug pricing
26 will provide substantial insight to further refine AMA messaging on this subject.

27
28 Finally, before the House of Delegates at its meeting, the Council on Medical Service presents a new
29 report on "Incorporating Value in Pharmaceutical Pricing" (CMS Report 5-I-16). This report proposes
30 a series of principles to guide the use of value-based drug pricing which the Council believes will
31 serve as a more impactful and politically viable approach on this issue than further delineating AMA
32 policy on Medicare drug price negotiation.

33
34 The Board of Trustees will continue to keep the HOD apprised of ongoing AMA advocacy and
35 grassroots efforts to help put forward solutions to make prescription drugs more affordable for all
36 patients.

APPENDIX

**METRICS FOR EVALUATING AMA POLICY
FOR INCLUSION IN AMA GRASSROOTS CAMPAIGN ON PHARMACEUTICAL COSTS**

- **Impact on patient access, safety and medication adherence**
Would the policy directly or indirectly impact patient access to necessary therapies and high-quality care, cost-sharing and medication adherence? Would the policy lead to a pharmaceutical marketplace that works better for patients? How would the policy impact innovation and the development of better treatment options for patients? Would the policy pose potential risks to patient safety?
- **Impact on physicians and physician practices**
How would the implementation of the policy impact physicians and physician practices?
- **Likelihood of successful implementation**
What is the likelihood that legislation or regulations to implement the policy will be successful on the state and federal levels? Would an advocacy campaign on the issue lend itself to the AMA partnering with patient organizations to achieve success?
- **Issue/Message cohesion**
If the task force considers multiple policies to feature in the advocacy campaign, are the policies complementary? Will they work together in media messaging and in a larger advocacy strategy?
- **Unique perspective of the AMA on the issue**
Is it appropriate for the AMA to take the lead on the issue? Does it make sense for physicians and patients to advocate on the issue? Can the AMA bring an effective, unique perspective to the table?
- **Alignment with strategic focus areas**
Does the policy support the ability of the AMA to improve health outcomes, create thriving physician practices, or create the medical school of the future?
- **Alignment with other AMA advocacy priorities**
How does the policy align with other AMA advocacy priorities?
- **Ability of grassroots advocates to understand the policy/combination of policies**
Will members of the AMA Physicians' Grassroots Network and the Patients' Action Network be able to understand the policy proposals we are asking them to help advance?
- **Ability to differentiate from political campaign messaging**
Will the AMA be able to effectively differentiate from the campaign messaging of presidential, federal and statewide candidates in its advocacy campaign on the issue? Could it be possibly interpreted that the AMA is endorsing proposals of a particular candidate?
- **Balanced impact on stakeholders involved in pharmaceutical pricing**
Would the policy impact and engage the range of stakeholders involved in pharmaceutical pricing, including but not limited to pharmaceutical companies, health plans and pharmacy benefit managers? Would an advocacy campaign on the policy align the AMA with one stakeholder while targeting another?

REPORT OF THE BOARD OF TRUSTEES

B of T Report 11-I-16

Subject: 2017 Strategic Plan

Presented by: Patrice A. Harris, MD, MA Chair

1
2 Our AMA is making progress on its multi-year strategy to achieve significant positive impact for
3 physicians, medical students and patients. The strategy, launched in 2013, identifies three areas of focus:
4 Improving Health Outcomes, Accelerating Change in Medical Education, and Shaping Care Delivery and
5 Payment for Professional Satisfaction and Practice Sustainability. These focus areas provide for tangible
6 and meaningful implementation of our AMA's mission to promote the art and science of medicine and the
7 betterment of public health.

8
9 Through this report, the Board of Trustees affirms AMA's multi-year strategic focus. This report
10 summarizes what is on the horizon for each of the focus areas in 2017 and highlights other work to
11 modernize the means through which physicians can engage in advancement of the mission.

12 13 CARE DELIVERY AND PAYMENT: 14 PROFESSIONAL SATISFACTION AND PRACTICE SUSTAINABILITY

15
16 For nearly two decades, work toward repeal of the sustainable growth rate (SGR) formula was a core
17 component of AMA's strategy. Since enactment of the Medicare and CHIP Reauthorization Act of 2015
18 (MACRA), our work has refocused – with even greater intensity – to ensure that MACRA's
19 implementation supports a health care system that delivers better care and more visible value while also
20 supporting a sustainable practice environment. The goal is to create a pathway for physicians to choose
21 from a broad array of alternative payment and health care delivery models, including viable fee-for-
22 service options.

23
24 Successful navigation and implementation of evolving public and private payment systems requires
25 heightened physician awareness, informed assessment of options, and, potentially, new ways of capturing,
26 analyzing and reporting practice information. To support physicians through this changing landscape and
27 improve care delivery and professional satisfaction, AMA will work in 2017 to:

- 28
29
- 30 • Advocate for legislative and regulatory changes that enhance prospects for physicians to succeed.
 - 31 • Generate awareness and encourage physicians to prepare for impending payment model changes.
 - 32 • Provide multi-modal, multi-channel physician education about what new payment model options
33 mean for physicians and patients.
 - 34 • Update the MACRA physician payment model evaluation tool, which was introduced in 2016,
35 and supplement it with additional resources that not only help physicians make informed
36 decisions, but also help them take steps to implement the decisions effectively.
 - 37 • Guide physicians toward the best outcome in value-based care systems and establish the AMA as
38 a valued source of support on issues spanning a wide range of care delivery and payment models.
 - 39 • Expand the resources delivered through the STEPS Forward: Practice Improvement Strategies
40 program to help physicians in a variety of practice settings learn new techniques to improve
practice workflow, patient care and professional satisfaction.

- 1 • Increase the awareness and importance of professional satisfaction and support the Quadruple
2 Aim through new research, partnerships, and resources to assist physicians throughout the various
3 settings and stages of their careers.
- 4 • Discover and promote the physician perspective across health technology sectors, directing
5 development for improved usability, productive access to data, and respect for the patient-
6 physician relationship.

7
8 With a view toward the longer-term horizon, in 2017 AMA will also expand current work toward
9 modernizing medical information coding systems that will give physicians access to data needed to
10 reliably report performance, assess financial risk and inform negotiations for new risk-sharing payment
11 models.

12 IMPROVING HEALTH OUTCOMES (IHO)

13
14 Initiatives focused on health outcomes underscore AMA's foundational commitment to improving the
15 health of the nation. Concentrating on risk factors for cardiovascular disease and type 2 diabetes, our
16 AMA is working with physicians and care teams to bring new approaches for anticipating, preventing,
17 and managing widely prevalent chronic conditions that often carry acute consequences for patients.
18

19
20 To achieve the scale required for this ambitious set of programs, AMA has developed multi-year strategic
21 relationships with the Centers for Disease Control and Prevention (CDC) and the American Heart
22 Association (AHA), whose national reach and influence reinforce and complement AMA resources. Our
23 shared goals with the CDC and the AHA include significantly increasing the number of physician
24 practices, health care systems and federally qualified health centers that:

- 25 • Screen patients for prediabetes and refer eligible patients to CDC-recognized diabetes prevention
26 programs (DPPs) as the preferred option for preventing type 2 diabetes, and
- 27 • Improve care for patients with hypertension to achieve and sustain 70 percent or higher blood
28 pressure control rates within the communities they serve.

29
30 AMA will expand collaboration with partner organizations to offer evidence-based products, tools and
31 services to support physicians, care teams, health system leaders and medical students in achieving the
32 health outcomes we seek. Materials are being developed and distributed for use in practice settings
33 ranging from small private practices to large integrated systems. Examples include resources available
34 through the AMA-AHA Target BP website (<http://targetbp.org/targetbp/participant-resources-and-tools/>)
35 as well as plans for a new AHA-AMA Target BP "Recognition Program" as a vehicle for engaging
36 healthcare delivery systems in improving blood pressure control nationally. We continue to define and
37 promote the "business case" for public and private payer coverage of proven interventions such as
38 diabetes prevention programs (for which Medicare announced coverage in 2016) and self-measured blood
39 pressure monitoring devices.

40
41 Involving patients is an important element of change as we will continue to seek venues to bring
42 messages to broad public audiences, such as was accomplished through the national prediabetes
43 awareness campaign launched in 2016.

44 ACCELERATING CHANGE IN MEDICAL EDUCATION (ACE)

45
46 The AMA is collaborating to accelerate change in medical education by creating a system that trains
47 physicians to meet the needs of today's patients and to anticipate future changes. The initiative has funded
48 major innovations at 32 medical schools and brought these schools together into a Consortium that shares
49 best practices and lessons learned. The Consortium is disseminating the proven transformation strategies
50 emerging from these leading medical schools across the medical education environment.
51

1 Highlights of major plans for 2017 include:

- 2 • Building on prototyping/models for the medical school of the future (faculty development;
3 developmental models for health system science and health data analytics; competency-based
4 assessment, etc.)
- 5 • Collaborating with other focus areas on student and trainee wellness; resilience/burnout; and new
6 models for linking students, physicians and communities in shared goals of chronic disease
7 management and health equity
- 8 • Developing work themes around transition to residency and transition to practice, including
9 exploration of new ideas with the National Residency Match Program

10
11 In parallel with implementation of ACE-sponsored education innovations, AMA along with participating
12 schools and partners will work in 2017 to develop a sustainable plan for the ACE Consortium into the
13 future, ready for implementation in 2018.

14 ENGAGING PHYSICIANS IN ADVANCEMENT OF THE MISSION

15
16
17 Continuing physician professional development is a cornerstone of the strategy for activating the focus
18 area objectives, which require changes in physician (and team) knowledge, skills and practice. The focus
19 area objectives and other national imperatives--such as reducing opioid-related harm and increasing
20 access to treatment for patients with opioid use disorders--require AMA to provide physicians and their
21 team members pragmatic educational offerings, tools, and leadership training designed to address real-
22 world practice and care delivery issues.

23
24 AMA's strategy in this domain calls for development of an improved Education Center portal and
25 platform over the next two years. New capabilities and an improved user experience will be introduced in
26 2017. The Introduction to the Practice of Medicine program, currently deployed in approximately 150
27 residency settings across the country, will also be modernized and incorporated into the Education Center
28 in 2017. As the multi-year effort progresses, our physician stakeholders will have access to educational
29 tools and resources from diverse sources through a highly functional platform tailored to individual needs,
30 accessible from desktops and mobile devices, with streamlined support for transcripts, reporting to
31 boards, employers and payers to serve credentialing, licensing and certification requirements.

32
33 Evidence of AMA mission impact continues to grow, creating an opportunity for AMA to refresh its
34 brand identify among physicians and other stakeholders. We will achieve this by linking relevant
35 offerings and activities throughout the career lifecycle of students, residents, and practicing physicians.
36 The goal is to strengthen the AMA brand through deeper stakeholder engagement. Traditional and
37 interactive/social/digital media will be deployed to create new connections, awareness, and opportunities
38 to interact with the AMA. More sophisticated monitoring of interactions also will yield insight into
39 physician preferences so that we can continuously improve services to physicians, residents and fellows,
40 and medical students so as to retain and grow our membership base.

41
42 The momentum that supports this multi-year strategy is a reflection of collaboration and shared
43 commitment across the AMA and the Federation of medicine, academic institutions, public and private
44 health sector organizations, technology innovators, physicians, and physicians in training. Together we
45 will chart a course for health care delivery that will improve the health of the nation.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Opinion 1-I-16

Subject: Modernized *Code of Medical Ethics*

Presented by: Ronald A. Clearfield, MD, Chair

1 At the 2016 Annual Meeting, the American Medical Association House of Delegates adopted the
2 recommendation of Council on Ethical and Judicial Affairs Report 2-A-16, “Modernized *Code of*
3 *Medical Ethics*.” The Council issues the Opinions of the modernized *Code*, which will appear in
4 full in AMA PolicyFinder and the next print edition of the *Code of Medical Ethics*.
5
6 The Council thanks the members of the House of Delegates who brought typographical errors in
7 the draft modernized *Code* to its attention. These have been corrected.
8
9 The Council wishes to advise the House that where appropriate throughout the Opinions of the
10 modernized *Code* the phrase “in keeping with ethical guidelines” has been replaced by the phrase
11 “in keeping with ethics guidance” for clarity. For example, Opinion 1.2.3, “Consultation, Referral,
12 and Second Opinions,” would read, “(b) Share patient’s health information in keeping with ethics
13 guidance on confidentiality.”

* Opinions of the Council on Ethical and Judicial Affairs will be placed on the Consent Calendar for informational reports, but may be withdrawn from the Consent Calendar on motion of any member of the House of Delegates and referred to a Reference Committee. The members of the House may discuss an Opinion fully in Reference Committee and on the floor of the House. After concluding its discussion, the House shall file the Opinion. The House may adopt a resolution requesting the Council on Ethical and Judicial Affairs to reconsider or withdraw the Opinion.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Opinion 2-I-16

Subject: Ethical Practice in Telemedicine

Presented by: Ronald A. Clearfield, MD, Chair

1 At the 2016 Annual Meeting, the American Medical Association House of Delegates adopted the
2 recommendation of Council on Ethical and Judicial Affairs Report 1-A-16, “*Ethical Practice in*
3 *Telemedicine.*” The Council issues this Opinion, which will appear in the next version of AMA
4 PolicyFinder and the next print edition of the *Code of Medical Ethics*.

5 6 1.2.12 Ethical Practice in Telemedicine

7
8 Innovation in technology, including information technology, is redefining how people perceive
9 time and distance. It is reshaping how individuals interact with and relate to others, including
10 when, where, and how patients and physicians engage with one another.

11
12 Telehealth and telemedicine span a continuum of technologies that offer new ways to deliver
13 care. Yet as in any mode of care, patients need to be able to trust that physicians will place
14 patient welfare above other interests, provide competent care, provide the information patients
15 need to make well-considered decisions about care, respect patient privacy and confidentiality,
16 and take steps to ensure continuity of care. Although physicians’ fundamental ethical
17 responsibilities do not change, the continuum of possible patient-physician interactions in
18 telehealth/telemedicine give rise to differing levels of accountability for physicians.

19
20 All physicians who participate in telehealth/telemedicine have an ethical responsibility to
21 uphold fundamental fiduciary obligations by disclosing any financial or other interests the
22 physician has in the telehealth/telemedicine application or service and taking steps to manage
23 or eliminate conflicts of interests. Whenever they provide health information, including health
24 content for websites or mobile health applications, physicians must ensure that the information
25 they provide or that is attributed to them is objective and accurate.

26
27 Similarly, all physicians who participate in telehealth/telemedicine must assure themselves that
28 telemedicine services have appropriate protocols to prevent unauthorized access and to protect
29 the security and integrity of patient information at the patient end of the electronic encounter,
30 during transmission, and among all health care professionals and other personnel who
31 participate in the telehealth/telemedicine service consistent with their individual roles.

* Opinions of the Council on Ethical and Judicial Affairs will be placed on the Consent Calendar for informational reports, but may be withdrawn from the Consent Calendar on motion of any member of the House of Delegates and referred to a Reference Committee. The members of the House may discuss an Opinion fully in Reference Committee and on the floor of the House. After concluding its discussion, the House shall file the Opinion. The House may adopt a resolution requesting the Council on Ethical and Judicial Affairs to reconsider or withdraw the Opinion.

1 Physicians who respond to individual health queries or provide personalized health advice
2 electronically through a telehealth service in addition should:

- 3
4 (a) Inform users about the limitations of the relationship and services provided.
5
6 (b) Advise site users about how to arrange for needed care when follow-up care is indicated.
7
8 (c) Encourage users who have primary care physicians to inform their primary physicians
9 about the online health consultation, even if in-person care is not immediately needed.
10

11 Physicians who provide clinical services through telehealth/telemedicine must uphold the
12 standards of professionalism expected in in-person interactions, follow appropriate ethical
13 guidelines of relevant specialty societies and adhere to applicable law governing the practice of
14 telemedicine. In the context of telehealth/telemedicine they further should:

- 15
16 (d) Be proficient in the use of the relevant technologies and comfortable interacting with
17 patients and/or surrogates electronically.
18
19 (e) Recognize the limitations of the relevant technologies and take appropriate steps to
20 overcome those limitations. Physicians must ensure that they have the information they
21 need to make well-grounded clinical recommendations when they cannot personally
22 conduct a physical examination, such as by having another health care professional at the
23 patient's site conduct the exam or obtaining vital information through remote
24 technologies.
25
26 (f) Be prudent in carrying out a diagnostic evaluation or prescribing medication by:
27
28 (i) establishing the patient's identity;
29
30 (ii) confirming that telehealth/telemedicine services are appropriate for that patient's
31 individual situation and medical needs;
32
33 (iii) evaluating the indication, appropriateness and safety of any prescription in keeping
34 with best practice guidelines and any formulary limitations that apply to the
35 electronic interaction; and
36
37 (iv) documenting the clinical evaluation and prescription.
38
39 (g) When the physician would otherwise be expected to obtain informed consent, tailor the
40 informed consent process to provide information patients (or their surrogates) need about
41 the distinctive features of telehealth/telemedicine, in addition to information about
42 medical issues and treatment options. Patients and surrogates should have a basic
43 understanding of how telemedicine technologies will be used in care, the limitations of
44 those technologies, the credentials of health care professionals involved, and what will be
45 expected of patients for using these technologies.
46
47 (h) As in any patient-physician interaction, take steps to promote continuity of care, giving
48 consideration to how information can be preserved and accessible for future episodes of
49 care in keeping with patients' preferences (or the decisions of their surrogates) and how
50 follow-up care can be provided when needed. Physicians should assure themselves how

1 information will be conveyed to the patient's primary care physician when the patient
2 has a primary care physician and to other physicians currently caring for the patient.
3

4 Collectively, through their professional organizations and health care institutions, physicians
5 should:

- 6
- 7 (i) Support ongoing refinement of telehealth/telemedicine technologies, and the
8 development and implementation of clinical and technical standards to ensure the safety
9 and quality of care.
 - 10
 - 11 (j) Advocate for policies and initiatives to promote access to telehealth/telemedicine
12 services for all patients who could benefit from receiving care electronically.
13
 - 14 (k) Routinely monitor the telehealth/telemedicine landscape to:
 - 15
 - 16 (i) identify and address adverse consequences as technologies and activities evolve; and
 - 17
 - 18 (ii) identify and encourage dissemination of both positive and negative outcomes.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 3-I-16

Subject: CEJA and House of Delegates Collaboration

Presented by: Ronald A. Clearfield, MD, Chair

1 Policy D-600.957 asks the AMA to evaluate:

2
3
4
5
6
7
8
9

- how the collaborative process between the House of Delegates and the Council on Ethical and Judicial Affairs can best be improved to allow HOD input to CEJA deliberation while still preserving CEJA autonomy; and
- how a periodic review of *Code of Medical Ethics* guidelines and reports can best be implemented.

10 Testimony supported looking more closely into the collaboration between the Council on Ethical
11 and Judicial Affairs and the House of Delegates and encouraged a more clearly delineated review
12 process for the *Code of Medical Ethics*. It also was noted that ethics guidance is intended to be
13 timeless.

14 RELEVANT AMA POLICY

15
16
17 AMA policy is largely silent with respect to the means by which CEJA should collaborate with the
18 House of Delegates. The Bylaws grant CEJA authority to interpret the Principles of Medical Ethics
19 (6.5.2.1) and to investigate and make recommendations to the House regarding “general ethical
20 conditions and all matters pertaining to the relations of physicians to one another or to the public”
21 (6.5.2.3). Bylaw 2.13.1.1 provides that all matters pertaining to the Principles of Medical Ethics,
22 including CEJA reports, be referred to the Reference Committee on Amendments to Constitution
23 and Bylaws. Bylaw 2.13.1.7.2 provides that CEJA Opinions be treated as informational and filed
24 and that motions may be made to extract an opinion and a request made to CEJA to withdraw or
25 reconsider it. Bylaw 2.13.1.7.2 also provides that the House may adopt, refer, or not adopt CEJA
26 reports, but that they may be amended only with the concurrence of the Council.

27
28 Policy G-615.040, “Opinions and Reports of CEJA,” provides that CEJA will present its opinions
29 as informational and may provide to the House an analysis of issues and explanation for its opinion
30 at the council’s discretion. G-615.040 also replicates provisions of Bylaw 2.13.1.7.2 regarding
31 treatment of CEJA opinions, as well as provisions regarding the treatment of CEJA reports.

32
33 CEJA’s internal administrative rules provide only that matters under consideration by the council
34 be treated as confidential until the council itself approves its report and recommendations. This has
35 been interpreted to mean that CEJA reports in development are confidential until the council itself

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

1 releases them, whether by formally presenting a report for House action or otherwise making a
2 report available for review and comment (eg, through the council's online forum).

3
4 CEJA PRACTICE

5
6 Independent of the special project to comprehensively review the *Code*, AMA ethics guidance is
7 regularly updated whenever House of Delegates adopts a CEJA report and the report's
8 recommendations are subsequently issued as an opinion, generally at the next meeting of the
9 House. This includes amendments to existing guidance in response to significant changes in
10 medical science or practice or to address newly raised questions about a particular ethics topic as
11 well as de novo reports on new topics. Normal House processes enable delegations to submit
12 resolutions asking CEJA to re-examine existing guidance.

13
14 Historically, in addition to the reference committee process and its Open Forum sessions at each
15 Annual and Interim Meeting, CEJA has used a variety of strategies to obtain input, including
16 individually inviting written review or presenting work in progress in small face-to-face meetings
17 with key stakeholders on a report-by-report basis. In response to concerns about opportunity to
18 provide input to the modernization of the *Code of Medical Ethics*, CEJA also scheduled special
19 informal "open house" sessions at both the 2015 Annual and Interim Meetings to enable delegates
20 to share comments in person.

21
22 Since 2012, CEJA has made materials available to a wider audience for input by posting content to
23 its online discussion forum (www.ama-assn.org/go/cejaforum), allowing anyone with an AMA
24 sign-on to read and post comments. CEJA alerts stakeholders from whom it particularly desires
25 comment that material is available for review online. In general, CEJA has restricted printing,
26 copying, or sharing of documents in development in keeping with its administrative rule regarding
27 confidentiality of work not yet approved by the council for presentation to the House.

28
29 Consistent with the experience of online posting of the delegate Handbook, CEJA has had only
30 limited success using its online forum as a means of engaging stakeholders. For the most part,
31 although there has usually been reasonable traffic to the site, few viewers have actually posted
32 comments. CEJA has heard concerns that the platform itself is cumbersome, and that document
33 protections that prohibited individuals from printing or copyediting material significantly reduced
34 the opportunity or ability to provide input.

35
36 OPPORTUNITIES TO ENHANCE COLLABORATION

37
38 Preserving CEJA's independence is essential to its role as the voice of ethics for the profession, and
39 flexibility in its work processes is important. As a practical matter, experience suggests that
40 opportunities to enhance collaboration between the House of Delegates and CEJA are somewhat
41 limited. An important consideration in this regard is timing.

42
43 Over the past several years, CEJA has systematized its process of developing reports in ways that
44 enable the council to seek input at different stages in the process, from an initial outline of salient
45 issues through a draft ethics analysis to draft recommendations. CEJA should take advantage of
46 this evolution to solicit input more proactively, especially by requesting comment on its outline of
47 issues and its draft recommendations. AMA's technology staff may be able to help identify
48 appropriate tools to enhance delegates' and members' opportunity to offer comment electronically.

49
50 However, it seems unrealistic to expect that significant active collaboration with the House as a
51 whole can take place outside the framework of Annual and Interim Meetings. In CEJA's

1 experience, there has been little to no response to materials available online well in advance of
2 meetings. With rare exceptions, it appears that delegations overall understandably deploy their
3 limited resources for reviewing proposed policy almost exclusively immediately in advance of
4 meetings—ie, only after the delegate Handbook has been posted. This limits the opportunity for
5 CEJA to engage around work in development, particularly because there is no mechanism for
6 incorporating work products in their “pre-final” stages into the Handbook.

7
8 For the House as a whole, dedicating some portion of the schedule at Annual and Interim Meetings
9 for delegations to share reflections in person seems to hold the best hope for meeting the perceived
10 need for additional or enhanced collaboration. The “open house” model actually worked well with
11 respect to modernizing the *Code*. It offered concerned delegates the opportunity to present critique
12 in person in an informal, collegial environment and allowed CEJA to engage in discussion of
13 points raised as well as to receive valuable feedback. Participants in the A-15 and I-15 open house
14 sessions appeared to find the Saturday morning time slot reasonably convenient.

15
16 Sessions could be publicized in the Speakers’ Letter and materials posted to CEJA’s forum
17 (without protection) for prospective participants to download and print—or could be requested
18 directly from staff by email. CEJA’s Open Forum would not be an appropriate venue given the
19 educational criteria the Open Forum must meet to receive *AMA PRA Category 1 Credit*[™] and the
20 fact that it competes with multiple other sessions on the Monday morning of Annual and Interim
21 Meetings.

22
23 The Council on Ethical and Judicial Affairs therefore proposes to convene “pilot” open house
24 sessions at the 2017 Annual and Interim Meetings; seek ways to enhance its online forum for input
25 between meetings; and evaluate the value of these activities as mechanisms for enhancing
26 collaboration.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

CEJA Report 4-I-16

Subject: Ethical Physician Conduct in the Media

Presented by: Ronald A. Clearfield, MD, Chair

- 1 Policy D-140.957 asks that American Medical Association (AMA):
2
3 1. Report on the professional ethical obligations for physicians in the media, including
4 guidelines for the endorsement and dissemination of general medical information and
5 advice via television, radio, internet, print media, or other forms of mass audio or video
6 communication;
7
8 2. Study disciplinary pathways for physicians who violate ethical responsibilities through
9 their position on a media platform; and
10
11 3. Release a statement affirming the professional obligation of physicians in the media to
12 provide quality medical advice supported by evidence-based principles and transparent to
13 any conflicts of interest, while denouncing the dissemination of dubious or inappropriate
14 medical information through the public media including television, radio, internet, and
15 print media.
16
17 The resolution seeks to address concerns about the conduct of physicians who make medical
18 information available to the public through various media outlets. The resolution focuses primarily
19 on the potential for medical information to influence behavior, the importance of ensuring the
20 accuracy of medical information, and the obligation to report unethical behavior among physicians.
21 It does not explicitly acknowledge conflict of interest, physicians' responsibilities with respect to
22 health promotion, or physicians' use of online and social media.
23
24 Council on Ethical and Judicial Affairs' (CEJA) deliberations on this topic are ongoing; CEJA
25 therefore intends to submit its final report at the 2017 Annual Meeting.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-I-16

Subject: National Drug Shortages: Update

Presented by: Bobby Mukkamala, MD, Chair

1 INTRODUCTION

2
3 Policy H-100.956, “National Drug Shortages,” directs the Council on Science and Public Health
4 (CSAPH) to continue to evaluate the drug shortage issue and report back at least annually to the
5 House of Delegates (HOD) on progress made in addressing drug shortages in the U.S. This
6 informational report provides an update on continuing trends in national drug shortages and
7 ongoing efforts to further evaluate and address this critical public health issue.

9 METHODS

10
11 English-language reports were selected from a PubMed and Google Scholar search from
12 September 2015 to August 2016, using the text term “drug shortages” combined with “impact,”
13 “crisis,” “oncology,” “chemotherapy,” “antibacterial,” “pediatric(s),” “nutrition,” and “parenteral.”
14 Additional articles were identified by manual review of the references cited in these publications.
15 Further information was obtained from the Internet sites of the U.S. Food and Drug Administration
16 (FDA), American Society of Health-System Pharmacists (ASHP), Government Accountability
17 Office (GAO), Pew Charitable Trusts, Generic Pharmaceutical Association, the Pharmaceutical and
18 Research Manufacturers of America (PhRMA) and by direct contact with key FDA and ASHP staff
19 who manage drug shortage issues on a daily basis.

21 BACKGROUND

22
23 The Council has issued six previous reports on drug shortages.¹⁻⁶ The findings and conclusions
24 from these reports are summarized in CSAPH Report 2-I-15.⁶ The remainder of this report will
25 update current information on drug shortages since that report was developed.

27 CURRENT TRENDS IN DRUG SHORTAGES

28
29 The two primary data sources for information on drug shortages in the United States continue to be
30 the Drug Shortage Resource Center maintained by ASHP in cooperation with the University of
31 Utah Drug Information Service and the Drug Shortage Program at the FDA.^{7,8} For a reminder on
32 how the ASHP and FDA information and statistics on drug shortages are developed, see Table 1.
33 The ASHP defines a drug shortage as “a supply issue that affects how the pharmacy prepares or
34 dispenses a drug product or influences patient care when prescribers must use an alternative agent.”
35 The FDA defines shortages as a period of time when the demand or projected demand for a
36 medically necessary drug in the United States exceeds its supply. Medically necessary drugs are
37 defined by FDA as “any drug product used to diagnose, treat, or prevent a serious disease or
38 medical condition for which there is no other drug that is judged to be an appropriate substitute or
39 there is an inadequate supply of an acceptable alternative.”

1 Because their criteria differ (the main distinction being the FDA’s definition of a “medically
2 necessary drug”), the ASHP site lists more drug shortages than the FDA site.

3
4 *American Society of Health-System Pharmacists*

5
6 As of September 13, 2016, ASHP’s Drug Shortage Resource Center identified 135 drugs in
7 shortage, down from 180 at the same time in 2015. Among these drug shortages, 17 products were
8 not commercially available at all.⁸ Sixty-nine manufactured drugs have been discontinued since
9 2010, an increase of 9 from a year ago. The top active shortages by drug class remain central
10 nervous system agents, electrolytes and nutritional components, antimicrobials, cardiovascular
11 drugs, and chemotherapeutic agents. For a longitudinal view of new drug shortages on an annual
12 basis, and the number of active drugs shortages quarterly, see the Appendix. Active shortages
13 include both new and unresolved drug shortages. According to ASHP, the number of new
14 shortages continues to decrease, while the number of active shortages has stabilized to a certain
15 degree.

16
17 *Food and Drug Administration*

18
19 As of September 13, 2016, the FDA reported that 61 drugs were currently in shortage (compared
20 with 67 one year ago), and 10 had been resolved.⁸ The latter are closely monitored because they
21 may be at risk for falling back into shortage. Based on passage of the Food and Drug
22 Administration Safety and Innovation Act (FDASIA) in 2012, companies are required to notify
23 FDA of a permanent discontinuance or an interruption in manufacturing of certain drug products
24 six months in advance, or if that is not possible, as soon as practicable. The shortage notification
25 requirement has apparently reduced the number of new shortages by allowing FDA additional time
26 to work with manufacturers to prevent shortages. The FDA’s drug shortages website lists drugs that
27 meet these criteria, reflecting shortage information supplied by manufacturers.⁸ A Final Rule
28 published on July 27, 2015 provides further guidance on the notification process and adds biologic
29 products to the requirements for notification about potential supply disruptions.⁹

30
31 Drug Shortages Metrics Reported by FDA. The FDA’s third annual report on drug shortages
32 (required by FDASIA) noted the following metrics during the first three quarters of calendar year
33 2015.¹⁰

- 34
35
- 36 • FDA was notified of 131 potential shortage situations by 47 different manufacturers,
37 comparable to the numbers reported in 2014.
 - 38 • 128 new drug shortages were prevented in the first three quarters of 2015, a 64% increase
39 over the comparable time period for 2014.
 - 40 • The review of 102 generic abbreviated new drug or supplemental applications was
41 expedited, comparable to the numbers reported in 2014.
 - 42 • 11 inspections were prioritized to address a drug shortage, comparable to the number
43 reported in 2014.
 - 44 • 11 fewer new drug shortages occurred in the first three quarters of 2015 (22) compared
45 with the same period in 2014 (33).
 - 46 • FDA exercised regulatory flexibility and discretion in 19 instances affecting 37 medically
47 necessary products. Most of these involved measures to mitigate risks such as removing
48 particulate matter, extra testing for quality, third-party oversight of production, provision
49 of special instructions to prescribers and/or patients, or approval of foreign sources. With
respect to the last of these mitigation strategies, the FDA now conducts regular virtual

1 meetings with their international regulatory counterparts to share information on drug
2 shortages and mitigation strategies impacting patients in other countries.

3
4 The FDA also has developed apps for both the iPhone and Android operating systems that provide
5 access to drug shortage information as well as notifications about new and resolved drug shortages.

6 7 *Reporting a Drug Shortage*

8
9 Physicians can directly [report](#) a drug shortage via the ASHP drug shortage website. Physicians can
10 directly report a drug shortage to the Center for Drug Evaluation and Research via email
11 (drugshortages@fda.hhs.gov) or by phone at 240-402-7770.

12 13 GAO REPORT

14
15 In a follow-up to its 2014 report on drug shortages, the Government Accountability Office (GAO)
16 evaluated trends in drug shortages from 2010-2015 in an effort to identify influential factors.¹¹ This
17 evaluation confirmed that the FDA had prioritized 383 new, abbreviated, and supplemental drug
18 applications to address drug shortages, mostly for sterile injectable products. The use of this
19 prioritization scheme was temporally associated with reductions in active and ongoing shortages.
20 Analysis of selected categories (i.e., sterile injectable anti-infective and cardiovascular drugs)
21 confirmed that shortages were strongly associated with previously identified key drivers, namely a
22 decline in the number of manufacturers, existence of a generic product, and an emergent problem
23 with manufacturing capability in at least one manufacturer that was sufficiently serious to cause a
24 warning letter to be issued. Shortages were more likely to affect generic drugs with low profit
25 margins, although drug price itself was not predictive in this study.

26 27 GENERIC PHARMACEUTICAL ASSOCIATION

28
29 Given that the majority of drug shortages involve generic products, the GPhA created a voluntary
30 approach called the Accelerated Recovery Initiative in 2013 intended to accelerate the recovery of
31 certain critical drugs in short supply.^{4,12} This multi-stakeholder approach relies on voluntary,
32 confidential communication between an independent third party (IMS Health) and pharmaceutical
33 companies involved in the manufacturing of generic injectable drugs in shortage. Additionally,
34 wholesalers, distributors, and the FDA can provide information to assist companies with making
35 timely decisions to help avert or mitigate a shortage. While this program is apparently still
36 operational, there are no publicly available reports evaluating its degree of success.¹²

37 38 CLINICAL IMPLICATIONS

39
40 Despite increasing success in preventing or mitigating drug shortages and an overall decrease in the
41 number of new drug shortages, critical drug shortages continue to occur across multiple therapeutic
42 categories. While the existence of a sole source manufacturer is a risk factor for shortages, it also
43 has been the focus of some recent exorbitant drug price escalations. Reviews of shortages affecting
44 the operation of emergency departments identified several intravenous formulations that remain in
45 short supply and are affecting patient care including certain opioid analgesics, antiemetics, selected
46 antimicrobials, benzodiazepines and other drugs used for rapid induction of anesthesia,
47 electrolytes, and local anesthetics.^{13,14} Shortages of various antidotes also have been noted, and the
48 implications of drug shortages for pediatric patients, those with cardiovascular disease or those
49 who are acutely ill have been studied.¹⁵⁻¹⁸ In some cases, work-arounds have been successful in
50 maintaining patient safety and achieving satisfactory clinical outcomes.¹⁹

1 SUMMARY

2

3 Manufacturers are notifying the FDA about potential disruptions in supply or shortages earlier than
4 in the past and the FDA is expediting the review of new applications intended to address shortages.
5 Accordingly, the total number of new drug shortages continues to decline and the extent of ongoing
6 shortages has stabilized over the past two years. However, the drug supply for many acutely and
7 critically ill patients in the United States remains vulnerable despite federal efforts.²⁰ Some
8 progress is being made, but permanent solutions remain elusive and beyond the control of
9 individual practitioners and the health care system.

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Table 1. Contrasting the FDA (CDER) and ASHP Drug Shortage Websites

	FDA	ASHP
Purpose	Provides information obtained from manufacturers about current shortages, estimated duration, and discontinuations and provides information about FDA's and other stakeholders' roles in addressing and preventing shortages	Notification of new shortages and status of ongoing shortages; drug shortage management resources
Audience	Public	Healthcare practitioners
Scope of shortage list	All drugs are listed that are confirmed to be a national shortage by FDA. A shortage is considered to be the period of time when the demand for the drug within the United States exceeds the supply of the drug. ^a	All drug and biologic shortages reported and confirmed with manufacturer that are national in impact.
Source of shortage report	Manufacturers notify FDA of production disruption and voluntarily provide updates. Reports are also received from ASHP and from public via drugshortages@cder.fda.gov Note: Manufacturer-provided information represents shortage status at drug firm level.	Voluntary reports from practitioners, patients, pharmaceutical industry representatives and others Note 1: Information is updated based on release dates from manufacturers. Note 2: Reports reflect status at healthcare provider level.
Criteria for inclusion on list	Manufacturers cannot meet current market demand for the drug based on information provided by manufacturers and market sales research. Drug listed are defined as "medically necessary."	(1) Shortage is verified with manufacturers and (2) affects how pharmacy prepares or dispenses a product, or (3) requires use of alternative drugs, which may affect patient care.
Criteria for resolving shortage	One or more manufacturers are in production and able to meet full market demand.	All manufacturers of the drug restore all formulations and dosage sizes to full availability. Note: Products are listed despite partial or restricted availability as supply chain disruptions can result in intermittent shortages at the provider or patient level.
Reason for shortage	Provided by manufacturers using reasons required by legislation. ^b FDA encourages firms to provide additional information about reasons and other information which, if proprietary, is nondisclosable without the firm's permission.	Provided by manufacturer, if willing to disclose. Note: May differ from FDA's due to different sources of information and legislation requiring FDA to use specified reasons
Other information	Estimated duration, links to regulatory information such as recalls and Dear Healthcare Provider Letters	Estimated duration, list of available products, implications for patient care and safety, shortage management strategies, therapeutic alternatives

^a Note: A separate shortage webpage for vaccines and some biologics is maintained by the Center for Biologics Evaluation and Research.

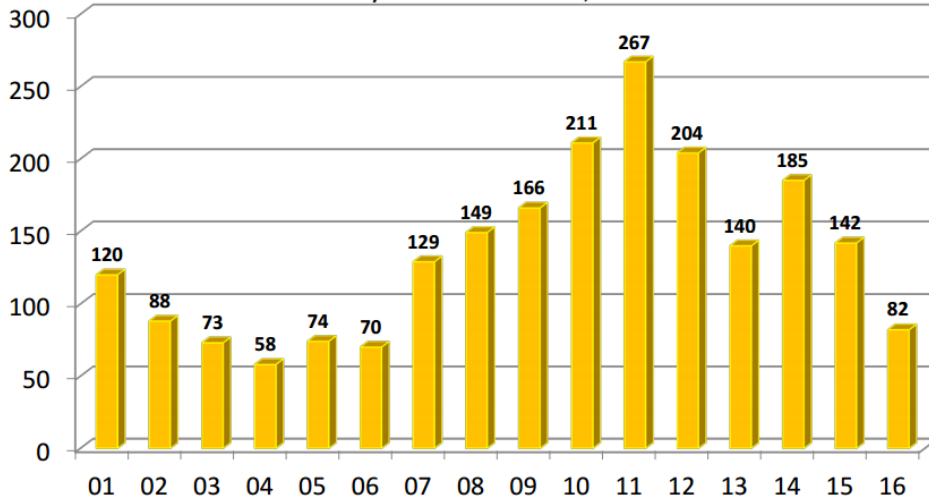
^b Categories include (a) requirement related to complying with good manufacturing practices; (b) regulatory delay; (c) shortage of an active ingredient

APPENDIX

National Drug Shortages

Annual New Shortages by Year

January 2001 to June 30, 2016

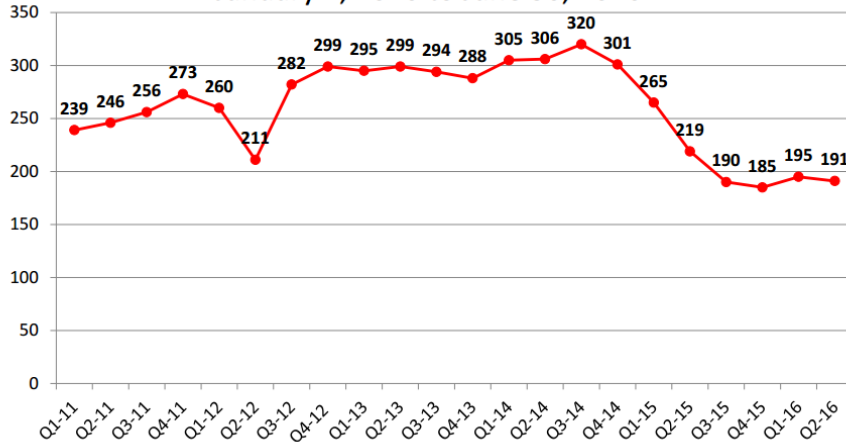


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National Drug Shortages

Active Shortages by Quarter

January 1, 2010 to June 30, 2016



Note: These data represent the count of active shortages on the last day of each quarter, and should not be interpreted as total shortages for that period.

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