



Sound Policy. Quality Care.

May 9, 2017

Scott Gottlieb, MD
Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

The undersigned members of the Alliance of Specialty Medicine write to congratulate you on your recent confirmation as Commissioner of the Food and Drug Administration (FDA).

As a practicing physician and hospitalist for many years, you have a deep understanding of the effect healthcare policy can have on patients as well as physicians. We believe you bring a wealth of knowledge to the position and will be an important advocate for the health care community.

With your wealth of experience having served in various capacities of the federal government, including as senior adviser for medical technology, director of medical policy development, and deputy commissioner for medical and scientific affairs at the FDA, we believe you will provide a steady hand at the FDA to ensure that our patients receive products that are both safe and effective. In addition, your broad-based policy experience will hopefully help to guide a more collaborative effort between the FDA and other entities, especially the Centers for Medicare and Medicaid Services (CMS).

Like you, our organization is dedicated to fostering patient access to the highest quality care. We look forward to continue working with you to improve health care policy for specialty physicians and their many patients. To assist you in these efforts, please find attached the Alliance of Specialty Medicine's **2017 Health Policy Principles**.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons

Enclosure

www.specialtydocs.org

info@specialtydocs.org

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American College of Mohs Surgery • American College of Osteopathic Surgeons • American Gastroenterological Association
American Society for Dermatologic Surgery Association • American Society of Cataract & Refractive Surgery • American Society of Echocardiography
American Society of Plastic Surgeons • American Urological Association • Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons • National Association of Spine Specialists

2017 Health Policy Principles

The Alliance of Specialty Medicine advocates for sound federal health care policy that fosters patient access to the highest quality specialty care and improves timely access to high-quality medical care for all Americans. As patient and physician advocates, the Alliance welcomes the opportunity to proactively participate in the formation of health and Medicare policy and looks forward to working with this Administration and Congress. Outlined below are key policy issues of importance to ensure access to specialty care and to promote transparency, oversight and accountability in the healthcare system.

Access to Specialty Care

Health care plans in the private market and Medicare should provide timely access to specialty care. Key to this theme is addressing narrow networks, providing comprehensive medical liability reform, allowing private contracting, maintaining a viable fee-for-service option, and addressing workforce shortages.

Ensure Network Adequacy

Patients face access to care barriers due to narrow health plan networks. Many times, unknown to patients, entire specialties are excluded from health plans or the number and mix of specialists and subspecialists are not adequate to meet the needs of the insured population. Networks should be sufficiently robust to ensure that an appropriate number of specialists and subspecialists per enrollee are available. Additionally, network directories should be updated in real-time and provide patients with clear, concise, and accurate information. Finally, decisions to remove a physician from the network without cause should not be made in the middle of a contract year. **Congress and the Administration should ensure appropriate oversight to hold insurers accountable to ensure patients have timely access to the right care, in the right setting, by the most appropriate health care provider.**

Enact Comprehensive, Meaningful Medical Liability Reform

Medical liability reform will help achieve health system savings by reducing the incentives for defensive medicine, and it will also protect physicians from unaffordable liability premiums. **Congress should enact comprehensive, meaningful medical liability reform based on the California or Texas models, which include reasonable limits on non-economic damages.** The Congressional Budget Office previously scored comprehensive and proven medical liability reforms as saving the federal government billions. In addition to these savings, such reforms will also improve patient access to specialty care — particularly high-risk specialties.

Maintain Viable Fee-for-Service Option

Americans should have a range of coverage options whether they get their health care in the private market, through an exchange plan, or under the Medicaid or Medicare programs. **Congress and the Administration should maintain a viable fee-for-service option, particularly since many communities do not have many health plans from which to choose and may not have an adequate number of specialists in those plans.** Furthermore, many alternative payment models are not appropriate for all medical specialists at this time; thus fee-for-service must be maintained.

Implement a Medicare Private Contracting Option

The current structure of Medicare restricts the ability of seniors to see the physician of their choice by limiting beneficiary access to all physicians. One way patients can overcome this hurdle is to “privately contract” for services directly with their physicians. Unfortunately, under current law, beneficiaries who wish to enter into these private contracts must pay for the service entirely out of their own pocket, despite having paid into Medicare for many years. Furthermore, if a physician has “opted out” of Medicare to contract privately — with even one patient — the physician is ineligible for Medicare reimbursement for two years. **Congress should eliminate the two-year Medicare exclusion for physicians who privately contract, and allow patients who privately contract to recoup the amount Medicare would otherwise pay for the service. Additionally, the Administration should explore opportunities to promote physician choice, including private contracting options, through the regulatory process or Medicare’s demonstration authority.**

Address Workforce Shortages

An appropriate supply of well-educated and trained physicians — both in specialty and primary care — is essential to ensure access to quality health care services for all Americans. Unfortunately, the nation is facing an acute shortage of physicians, due to an aging population and the expansion of health insurance coverage through the Affordable Care Act (ACA). And while medical schools in the U.S. have increased their enrollments, and additional medical and osteopathic schools have been established, the number of Medicare-funded resident positions has been capped by law at 1996 levels. To ensure an adequate supply of physicians and allow the graduate medical education system to operate optimally, **Congress should pass legislation increasing the number of Medicare-supported GME residency slots by 15,000 over five years and directing half of the newly available positions to training in shortage specialties.**

Transparency, Accountability and Oversight

Promoting transparency, accountability and oversight must be an integral part of our healthcare system. Key to this theme are repealing the Independent Payment Advisory Board (IPAB), providing appropriate oversight of federal agency activities, and ensuring that transparency does not disrupt medical education activities.

Repeal the Independent Payment Advisory Board

Established by the ACA, the IPAB is a 15-member government board — whose members are appointed by the president — with little or no clinical expertise or the oversight required to protect access to care for our country's seniors, has only one job: to arbitrarily cut billions of dollars from Medicare. Even worse, if no board is appointed, which is the situation right now, the Secretary of Health and Human Services has the sole authority to make these decisions. Proposed spending cuts automatically go into effect if Congress does not replace the recommendations with cuts of equal magnitude. Congress only has a very short time in which to pass its substitute proposal — making it a virtual certainty that the board's recommendations would be adopted. **The Alliance strongly supports repealing IPAB, which inappropriately delegates Congress' oversight responsibilities to an unaccountable board of government bureaucrats.** Medicare payment rates are already well below market rates, and it will likely only get worse. The IPAB solution will further ratchet down the costs, without care taken to ensure that our seniors receive the quality health care that they need and deserve. Important healthcare decisions must not be made with little clinical expertise, resources, or the oversight required to ensure that seniors are not placed in jeopardy.

Refine the Authority of the Center for Medicare and Medicaid Innovation

The Center for Medicare and Medicaid Innovation (CMMI) was established to provide a robust research and development platform to experiment and evaluate new payment and delivery approaches. Concerns over both the scale and scope of CMMI's recent demonstrations and its claim of authority to expand and mandate demonstrations nationwide and, in effect, enact permanent policy changes, have raised significant alarm among health care stakeholders, including specialty physicians. **The statutory authority for CMMI should be refined to ensure that demonstration authority is not overly broad and that participation in CMMI-approved payment models is voluntary.** CMMI should be used to test policies and not to advance sweeping new policies without appropriate congressional oversight.

Ensure Transparency and Medical Specialty Representation on the U.S. Preventive Services Task Force

Created in 1984, the U.S. Preventive Services Task Force (USPSTF) is an independent, panel of national experts in prevention and evidence-based medicine. The Task Force makes recommendations about clinical preventive services such as screenings, counseling services, and preventive medications, and insurers are mandated to cover preventive services recommended by the USPSTF. To make the USPSTF process more transparent and subject to

oversight, **Congress should pass the bipartisan “USPSTF Transparency and Accountability Act” (HR 539) which includes critical reforms.** The legislation would ensure input from medical specialists, regularly engage interested stakeholders and scientific and medical experts in the subject matters under review.

Exempt CME from Physician Sunshine Act Reporting

The ACA outlined specific exclusions from Physician Sunshine Act reporting. As the law was implemented, the Centers for Medicare and Medicaid Services (CMS) determined that accredited continuing medical education (CME) and reprints of peer-reviewed journal articles and medical textbooks do not directly benefit patients nor are they intended for patient use and therefore must be reported in the same manner as cash payments. The Alliance supports physicians’ access to independent educational resources and accredited or certified CME that are important to upgrade knowledge and skills and improve patient outcomes. **Congress should exempt peer-reviewed medical journal reprints, textbooks, and independent continuing medical education from Sunshine Act reporting.**

Provisions Important to Maintain in the Healthcare System

A careful review and adoption of thoughtful improvements to the ACA are essential to address the ongoing shortcomings of the healthcare delivery system. The Alliance has outlined a number of substantive concerns with the ACA before it was passed and enacted. As Congress works to improve the healthcare system, the Alliance believes the following provisions should be maintained to ensure access to affordable health insurance and access to specialty medicine:

- Maintain the elimination of pre-existing condition exclusions;
- Provide adequate access to specialty care through any benefit package;
- Protect against the rescission of health coverage;
- Ensure continuity in Medicaid coverage for children who go in and out of the system;
- Ensure coverage for routine services provided in conjunction with clinical trials;
- Ensure access and coverage of preventive screening services; and
- Prohibit annual and lifetime coverage limits.