

December 15, 2016

The Honorable Donald J. Trump
President-Elect

The Honorable Mike Pence
Vice President-Elect
1717 Pennsylvania Ave NW.
Washington, D.C. 20006

RE: Regulatory Reform Legislation in the 115th Congress

Dear President-Elect Trump and Vice President-Elect Pence,

On behalf of the American Dental Association (ADA), congratulations on your victory in November. As the oldest dental organization in America and the representative of over 159,000 dentists, the ADA is looking forward to working with the Trump Administration on a great many issues affecting oral health care in America.

The Association believes that in too many cases unnecessary federal regulations contribute to the cost of providing care making it more difficult for our members to deliver oral health care services at an affordable price. As the 115th Congress considers Regulatory Reform legislation in 2017, the ADA requests your consideration of several important health care regulations that must be rescinded or amended to ameliorate the adverse impact on dentists and their patients.

Ordering and Referring (Medicare)

Providers who order covered clinical laboratory services or imaging services for Medicare-eligible patients must be enrolled in Medicare's Provider Enrollment, Chain and Ownership System (PECOS) or opt-out of Medicare¹. By this rule change not only do providers that perform services covered by Medicare have to be enrolled in Medicare but also any provider that only orders tests or imaging services. The ADA estimates that fewer than 4% of all dentists provide Medicare services and are thus enrolled in Medicare. This is primarily because so few dental services are covered under Medicare.

The ADA supports efforts to reduce fraud, waste or abuse in any program; however, there is a dubious connection between enrolling dentists who only refer patients and program integrity. Dentists who only order tests and services do not receive Medicare reimbursement and are

¹ RIN 0938-AQ01 - Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements - Federal Register Vol. 75, No. 86, Wednesday, May 5, 2010, pages 24437 – 24449. Interim Final Rule.

unlikely to order same for patients without good cause. There is no potential for fraudulent billing if there is no billing. CMS already has access to the information needed to maintain program integrity through the dentists' National Provider Identifier (NPI) numbers and adverse event reporting maintained through the National Practitioner Data Bank (NPDB). **The ADA recommends that dentists who are not participating in Medicare be exempt from the Medicare Ordering and Referring requirements.**

Medicare Part D

Concerning Medicare Part D², the ADA shares the concerns of the Centers for Medicare and Medicaid Services (CMS) concerning fraud, waste and abuse. However, there is no need to require dentists to go through the enrollment process to ensure CMS has the information necessary to address fraud and abuse concerns. For example, CMS already has access to the information needed to maintain program integrity through the dentists' National Provider Identifier (NPI) numbers and adverse event reporting maintained through the National Practitioner Data Bank (NPDB). **The ADA supports excluding dentists and other health care professionals not participating in Medicare from the Medicare Part D enrollment requirements.**

Regulation Implementing Section 1557 Affordable Care Act

The U.S. Department of Health and Human Services, Office for Civil Rights (OCR) released the final rule on Section 1557³ providing for nondiscrimination in health care. The ADA strongly supports nondiscrimination in health care and equal access to health care for all patients without regard to race, color, national origin, sex, age, religion or disability. However, it has proven exceedingly difficult to advise ADA members on compliance with the final rule. ADA believes the OCR rule is unnecessary. The statute is already in effect and regulations are not required to implement the statute. **The ADA recommends that OCR simply enforce §1557 as written, which can be done without the promulgation of regulations. If the regulation is not**

² RIN 0938-AR37- 42 – CFR Parts 409, 417, 422, et al. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule – Federal Register / Vol. 79, No. 7 / Friday, January 10, 2014
Federal Register / Volume 79, Number 100, Friday, May 23, 2014 - 42 CFR Parts 417, 422, 423, et al. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule

³ Section 1557 of the ACA states an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).

This nondiscrimination provision applies portions of the following statutes to federal funded healthcare: title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794). The U.S. Department of Health and Human Services published a final rule under Section 1557 that applies to health programs and activities that receive federal financial assistance from HHS, with limited exceptions. U.S. Department of Health and Human Services Office for Civil Rights, *Nondiscrimination in Health Programs and Activities*, 46 CFR Part 92

rescinded, the Association recommends a small business exception (25 employees or fewer).

Requirement for Providers Participating in Medicare Advantage Programs to Enroll in Medicare

This final rule⁴ will require providers or suppliers that furnish health care items or services to a Medicare enrollee who receives his or her Medicare benefit through a Medicare Advantage (MA) organization to be enrolled in Medicare and be in an approved status. CMS states that this final rule is necessary to prevent fraud, waste, and abuse and to protect Medicare enrollees by carefully screening all providers and suppliers, especially those that potentially pose an elevated risk to Medicare, to ensure that they are qualified to furnish Medicare items and services.

This rule, as currently written, is not necessary to reduce the potential for fraud, waste and abuse and it undermines patient choice.

- The ADA supports efforts to reduce fraud, waste or abuse in any program. However, as these MA plans are administered by private entities the ADA believes they are already ensuring the integrity of the claims submitted and their provider enrollment processes are sufficient to prevent fraud.
- This rule, which precludes a patient's right to seek treatment from a non-network provider, will disrupt established patient-provider relationships.

ADA seeks repeal of this rule to ensure that providers of covered services in Medicare Advantage plans but who are not in-network providers may continue to treat patients who make the choice to see these out-of-network providers. Repeal will also ensure that out-of-network providers will not be subject to Medicare enrollment requirements in the future.

SAMHSA Recordkeeping/Confidentiality Mandate

The Substance Abuse and Mental Health Services Administration (SAMHSA) issued a proposed rule⁵ on February 9, 2016, to expand federal regulations regarding the confidentiality of patient records associated with substance abuse. Current law requires federally assisted substance use disorder programs to protect the confidentiality of alcohol and drug abuse patient

⁴ 42 CFR Parts 405, 410, 411, 414, 417, 422, 423, 424, 425, and 460

[CMS-1654-F]
RIN 0938-AS81

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements. Final Rule
DATES: These regulations are effective on January 1, 2017.

⁵ Confidentiality of Substance Use Disorder Patient Records; Proposed Rule. February 9, 2016 (81 Fed. Reg. 6988)

records. The agency is proposing expanding the regulations to cover certain health care practices that provide substance abuse disorder diagnosis, treatment or referral.

Dentists are providing only screening, brief intervention and referral services to help patients with substance use disorders find appropriate treatment. These services are offered voluntarily and without compensation. Many dental practices are solo and small group practices. It may be impossible for such practices to determine with certainty whether the proposed rule applies to them, and if so, which patient information needs to be protected, and what the proposed rule requires them to do. By requiring an entity to restrict staff access to data about substance abuse disorders, the proposed rule overlaps HIPAA's "minimum necessary" requirement, but does not provide the flexibility that HIPAA allows to develop and implement reasonable and appropriate safeguards. **The ADA urges the Substance Abuse and Mental Health Services Administration not to adopt the proposed rule, or, if the proposed rule is adopted, to exempt dental practices.**

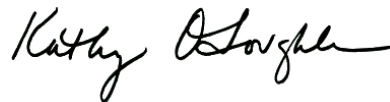
Thank you for your consideration of the ADA's requests.

If you have any questions or require additional information concerning the above requests, please contact Mr. Thomas Spangler at spanglert@ada.org or (202)789-5179.

Sincerely,



Gary Roberts, D.D.S.
President



Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

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