July 25, 2011

Donald M. Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Electronic Prescribing (eRx) Incentive Program; RIN 0938-AR00

Dear Dr. Berwick:

The undersigned organizations are pleased to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposal to modify the 2011 electronic prescribing (eRx) incentive and 2012 eRx penalty program. **While we appreciate CMS' steps to modify these programs, we are concerned that more changes are needed, including establishing an additional eRx reporting period in 2012 and not applying penalties until 2013; otherwise, a significant number of physicians and other eligible professionals (EPs) will be unfairly penalized starting on January 1, 2012.**

CMS is proposing to: modify the 2011 eRx measure for the 2011 incentive and 2012 penalty programs; provide additional significant hardship exemption categories for EPs and group practices so they can request an exemption during 2011 to avoid the 2012 eRx payment adjustment; and extend the deadline for submitting requests for consideration for the two significant hardship exemption categories for the 2012 eRx payment adjustment, which was finalized in the 2011 Medicare Physician Fee Schedule final rule. We believe that these immediate steps to modify the eRx program are helpful. **However, it is important to keep in mind that requiring reporting the year before the penalty program starts, not creating adequate exemption categories, and last minute modifications create confusion and do not allow enough time to educate physicians on steps they need to take to avoid eRx penalties in 2012.** How CMS handles the education, implementation, and administration of its programs greatly affects whether the policy that CMS is trying to implement is embraced by the physician community. The education and outreach on the e-prescribing program has been challenging given CMS' sudden change to the program requirements. Based on physician responses to date, we are concerned that a significant number of physicians will face eRx penalties because of the timing of the program adjustments and confusion over the program requirements.

In accordance with President Obama's January 18, 2011, Executive Order calling on federal agencies to reassess and streamline regulations, CMS has an opportunity to make the eRx penalty program fair and reasonable and better align the eRx and Medicare/Medicaid EHR incentive programs in order to minimize the financial and administrative hardships created by the various, overlapping Medicare incentive

and penalty programs currently underway. The eRx program is a perfect example of how critical it will be to pursue reasonable, achievable requirements, align the requirements for the various incentive programs currently underway in order to simplify the process for physicians, and coordinate efforts early-on when it comes to educational outreach to physicians and patients on these health IT programs.

Modification to the eRx measure

The law that established the Medicare eRx program, the "Medicare Improvements for Patients and Providers Act of 2008" (MIPPA) (P.L. 110-275), includes Medicare incentives and penalties to promote the adoption and use of eRx. An EP (or group practice participating in the eRx group practice reporting option (GPRO)) who is a successful e-prescriber during 2011 can qualify for an incentive payment equal to 1 percent of their total estimated Medicare Part B Physician Fee Schedule allowed charges for covered professional services furnished during the 2011 reporting period. In 2012, a 1 percent Medicare payment reduction based on the total Medicare Part B allowed charges (1.5 percent reduction in 2013 and 2 percent reduction in 2014) will be levied against EPs and group practices who are eligible for eRx incentives but choose not to participate or do not successfully participate in the eRx program.

CMS has defined a qualifying eRx system for the purposes of the eRx incentive and penalty programs as a system that is capable of performing the following four specific functionalities:

- Generates a complete active medication list incorporating electronic data received from applicable pharmacies and pharmacy benefit managers (PBMs), if available.
- Allows EPs to select medications, print prescriptions, electronically transmit prescriptions, and conduct alerts (that is, written or acoustic signals to warn the prescriber of possible undesirable or unsafe situations including potentially inappropriate doses or routes of administration of a drug, drug-drug interactions, allergy concerns, or warnings and cautions) and this functionality must be enabled.
- Provides information related to lower cost therapeutically appropriate alternatives (if any) (that is, the ability of an eRx system to receive tiered formulary information, if available, would again suffice for this requirement for 2011 and until this function is more widely available in the marketplace).
- Provides information on formulary or tiered formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan, if available.

In addition, a qualifying eRx system must convey the information above using the standards currently in effect for the Medicare Part D eRx program, including certain National Council for Prescription Drug Programs (NCPDP) standards.

CMS is proposing to expand the definition of a qualifying eRx system so that EHR technology under the Medicare/Medicaid EHR incentive program can also be recognized

as a qualifying system under the eRx program. For the purposes of reporting the current eRx quality measure during 2011 for incentives and for avoiding the 2012 eRx penalty, CMS has indicated that nothing precludes EPs (or a group practice) who already have certified EHR technology that meet the four functionalities described above from using the certified EHR technology for the purposes of the eRx Medicare incentive program. CMS further indicates that if the proposed rule is finalized later this year, using certified EHR technology will be acceptable for eRx in future reporting years even if the certified EHR does not meet the four specific functionalities. **We strongly support CMS' proposal to recognize EHR technology certified under the Medicare/Medicaid EHR incentive program as a qualifying system under the eRx incentive and penalty programs.** This recognition is an example of the importance of synchronizing the overlapping eRx and EHR programs so that physicians do not have to purchase an eRx system just to avoid penalties, and can invest in EHR technology that does more than just enable eRx.

Addition of significant hardship exemption categories for avoiding the 2012 eRx penalty

In the 2011 Medicare Physician Fee Schedule final rule, CMS finalized the program requirements for the 2012 eRx penalty program. To avoid an eRx penalty in 2012, CMS is requiring that an EP report the eRx G-code, G8553, at least 10 times for applicable Medicare office visits and services for the January 1, 2011 to June 30, 2011 reporting period. CMS also indicated that the 2012 eRx penalty would not apply to the following individuals: (1) an EP who is not a doctor of medicine, doctor of osteopathy, podiatrist, nurse practitioner, or physician assistant as of June 30, 2011; (2) an EP who does not have at least 100 cases (that is, Medicare Part B claims for patient services) containing an encounter code that falls within the denominator of the eRx measure for dates of service between January 1, 2011 and June 30, 2011; or (3) an EP who does not have prescribing privileges and reports the G-code, G8644 (code for not having prescribing privileges) at least one time on an eligible claim prior to June 30, 2011.

CMS also finalized that the 2012 eRx penalty would not apply to an individual EP or group practice if less than 10 percent of an EP's or group practice's estimated total Medicare Part B allowed charges for the January 1, 2011 to June 30, 2011 reporting period are comprised of services that appear in the denominator of the 2011 eRx measure. In addition, CMS finalized two circumstances under which an EP or group practice can request consideration for a significant hardship exemption from the 2012 eRx penalty: the EP or group practice practices in a rural area with limited high speed Internet access; or the EP or group practice practices in an area with limited available pharmacies for eRx.

The American Medical Association (AMA) along with multiple state and specialty medical societies, continually expressed serious concerns over the backdating of the 2012 eRx penalty program to require reporting in 2011, and the lack of adequate exemption categories for physicians who would have difficulty complying with the eRx program requirements through no fault of their own. Moreover, physicians who are or plan to participate in the EHR incentive program would now face separate, duplicative eRx reporting requirements due to CMS' lack of coordination of these various

incentive programs. These physician groups urged CMS to synchronize the overlapping Medicare incentive programs so that, for example, eligible physicians who participate in the Medicare EHR incentive program would be exempt from the Medicare eRx penalties, and create more exemption categories for physicians who because of the nature of their practice or the limitations of the eRx program requirements would be unfairly penalized under the eRx penalty program.

We support both the existing exemption categories specified above and the following proposed new exemption categories:

- The physician is registered to participate in the Medicare or Medicaid EHR incentive program and has adopted certified EHR technology.
- The physicians is unable to e-prescribe due to local, State, or Federal law or regulation.
- The physician infrequently prescribes (e.g., prescribe fewer than 10 prescriptions between January 1, 2011 –June 30, 2011).
- There are insufficient opportunities to report the eRx measure due to program limitations (e.g., a surgeon who e-prescribes but does not frequently use the service codes allowed under the program).

We also support CMS' decision to create general exemption categories and to assess exemption requests on a case by case basis, given that physicians have varying practices and must comply with varying state and local requirements. We do, however, recommend that CMS include the following clarifications and/or examples in the final rule:

- Under the "Registered to participate in the Medicare or Medicaid EHR incentive program and has adopted certified EHR technology" exemption category, physicians should be provided with the flexibility to provide the serial number or certification number of the certified EHR technology or any other information readily available to them that would identify or verify the specific EHR product that has been purchased in 2011 or 2012 for the Medicare or Medicaid EHR incentive program. In addition, we recommend that CMS clarify that EPs can register for the EHR incentive program in one year (e.g., 2011) and attest to meeting the meaningful use EHR incentive program requirements in the same year OR a following year (e.g., 2012, 2013, or 2014).
- Under the "Inability to electronically prescribe due to local, state, or federal law or regulation" exemption category, CMS should clarify that physicians who are unable to e-prescribe controlled substances because their eRx application/software is not yet compliant with the DEA and/or state requirements are eligible to apply for this exemption.
- Under the "There are insufficient opportunities to report the eRx measure due to program limitations" exemption category, CMS should clarify that a physician that e-prescribes for his/her patient but the e-prescription does not occur on the same day of the encounter with the patient would be eligible to apply for this eRx exemption.

We recommend that in the final rule, CMS make it clear that physicians must apply for at least one exemption but are allowed to apply for more than one exemption in order to avoid the 2012 eRx penalty. **We also strongly recommend that CMS maintain these exemption categories throughout the duration of the eRx penalty program (through 2014).**

We continue to urge CMS to add an exemption category for physicians who are currently eligible for Social Security benefits or will be eligible for Social Security benefits by 2014. It will be economically burdensome for physicians who intend to retire in the next several years to install and use an eRx system. We are also concerned that many of these physicians may decide to close their Medicare fee-for-service panels or opt out of Medicare to avoid penalties during the end stage of their clinical careers, which would adversely affect access to care for our nation's elderly and disabled. **Physicians who are currently eligible for Social Security retirement benefits or will be eligible for Social Security retirement benefits by 2014 should have the opportunity to apply for an exemption.**

In addition, we recommend that CMS allow physicians the opportunity to apply for an exemption if they did e-prescribe in accordance with the program requirements but their claim submissions were missing the G8553 code due to administrative or system errors or they mistakenly included a 2009 eRx G code rather than the G8553 code on their claims.

CMS should add an additional reporting period in 2012 to avoid the 2012 eRx penalty

We strongly urge CMS to add an additional reporting period in 2012 to provide physicians with more time to meet the required reporting of 10 G8553 codes to avoid an eRx penalty. The Physician Fee Schedule Final Rule was published in November, 2010, which left little time to educate physicians on the 2011 eRx reporting requirements for avoiding penalties in 2012. Furthermore, CMS' educational campaign in 2010 was extremely misleading because CMS indicated to physicians that they could not participate in both the Medicare eRx incentive program and the Medicare meaningful use EHR incentive program in the same year. Despite our efforts to reach and educate every physician who may be adversely affected by the Medicare eRx penalty program, more needs to be done to educate physicians, especially now on the proposed modifications to the eRx penalty program. **We strongly urge CMS to establish an additional reporting period in 2012 (e.g., January 1, 2012 – June 30, 2012) so that physicians have an additional opportunity to successfully e-prescribe to avoid the 2012 eRx penalty.**

CMS should establish a better mechanism for recouping money based on the eRx penalty

We continue to assert that there should be no penalties applied until 2013 against a physician facing a 2012 eRx penalty. Moreover, applying a 1 percent cut to all physicians who do not successfully report is an unworkable solution. CMS has indicated

that they will not publish separate payment schedules and limiting charges reflecting the application of the penalty. The only way physicians would know what their reduced allowed charges and their patients' copayments would be is by waiting for the Remittance Advice from Medicare. This would seriously complicate what is already likely to be a logistical nightmare, leading thousands of physicians to think that Medicare is paying them incorrectly and thousands of patients being charged incorrectly. As you know, many physicians collect copayments at the time of service and it would add greatly to their costs if they had to change to billing for them weeks later after the Remittance Advice is received. At a time when everyone is looking for more transparency in patient cost-sharing, this is a major step backwards. **CMS pays out eRx incentives following the conclusion of the reporting period. We urge CMS to apply this same protocol for the eRx penalty program by only requiring physicians who are subject to 2012 penalties to repay the amount owed after the calendar year 2012 reporting period has concluded.**

CMS should extend the deadline for applying for exemption(s) and establish an appeals process

We support CMS' decision to enable physicians to request an exemption from the 2012 eRx penalty via a web-portal tool for all significant hardship exemption requests, including the two current hardship exemption categories. **Given that CMS' proposed deadline, October 1, 2011, for applying for an exemption is just around the corner, we urge CMS to extend the deadline for applying for exemption(s) through December 31, 2011. Physicians should also be able to request an exemption by phone or in writing.** We believe that significant physician outreach and education will be critical to ensure that physicians and other EPs are aware of the significant modifications to the eRx program requirements, including the additional exemption categories. **Therefore, we urge CMS to collaborate with physician organizations in order to develop uniform outreach materials in a timely manner since the deadline to apply for an exemption is just several months away.**

We agree with CMS' proposal to limit the information that an EP or group practice would have to provide in order to apply for an exemption. CMS' proposal to collect: identifying information (e.g., TIN, NPI, name, mailing address and e-mail address of all affected EPs), the significant hardship exemption categor(ies) above that apply, a brief justification statement, and an attestation of the accuracy of the information provided is more than enough information to justify an exemption. Once CMS has completed their review of the physician's request for an exemption and made a decision, CMS should notify the EP or group practice within two weeks of CMS' decision to accept the exemption request. **We strongly urge CMS to establish an appeals process for EPs and group practices whose request for a significant hardship exemption is denied.**

Thank you for the opportunity to provide comments on CMS' proposed changes to the eRx program. Should you have questions about these comments, they can be directed to Jennifer Shevchek, AMA's Assistant Director, Federal Affairs, at jennifer.shevchek@ama-assn.org or 202-789-4688.

Sincerely,

American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Home Care Physicians
American Academy of Ophthalmology
American Academy of Otolaryngology – Head and Neck Surgery
American Academy of Pediatrics
American Academy of Physical Medicine and Rehabilitation
American Association of Clinical Endocrinologists
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Cardiology
American College of Chest Physicians
American College of Gastroenterology
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Physicians
American College of Rheumatology
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Geriatrics Society
American Medical Association
American Medical Group Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Psychiatric Association
American Osteopathic Academy of Orthopedics
American Society for Gastrointestinal Endoscopy
American Society for Radiation Oncology
American Society for Surgery of the Hand
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Society of Plastic Surgeons
American Thoracic Society
American Urological Association
Congress of Neurological Surgeons
Heart Rhythm Society
Infectious Diseases Society of America
Joint Council of Allergy, Asthma and Immunology
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Hospital Medicine
Society of Interventional Radiology
The Endocrine Society

Medical Association of the State of Alabama
Alaska State Medical Association
Arizona Medical Association
Arkansas Medical Society
California Medical Association
Colorado Medical Society
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Florida Medical Association Inc
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Louisiana State Medical Society
Maine Medical Association
MedChi, The Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
New Hampshire Medical Society
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
Medical Society of Virginia

Washington State Medical Association
West Virginia State Medical Association
Wisconsin Medical Society
Wyoming Medical Society