March 7, 2014

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4159–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: **Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs**

Dear Administrator Tavenner:

The American College of Physicians (ACP) appreciates this opportunity to comment on the above referenced Medicare drug benefit proposed rule. ACP is the largest medical specialty society and second largest physician membership organization in the United States, representing 137,000 internal medicine physicians who specialize in primary and comprehensive care of adolescents and adults and medical students who are considering a career in internal medicine.

The addition of the drug benefit to both the Medicare Advantage and traditional Medicare programs in 2006 significantly improved access to life-saving and life-improving medications to beneficiaries. We appreciate the Centers for Medicare and Medicaid Services' (CMS) efforts, through this proposed rule, to improve how the benefit is being delivered and to help ensure the benefit remains available to beneficiaries for many years to come. The College makes the following recommendations regarding indicated sections of the proposed rule to help inform CMS' efforts towards these goals:

- **Drug Categories or Classes of Clinical Concern and Exceptions** --- CMS is proposing to remove protected formulary status for 2015 to the classes of antidepressant and immunosuppressant drugs, and for antipsychotic drugs in the near future following a review of "transitional considerations". The College appreciates CMS' efforts through these proposed changes to be good stewards of limited healthcare resources, while at the same time attempting to ensure ---through multiple layers of beneficiary protections --- that reasonable access to the right medications at the right time remains intact. We are also aware of and respect the concerns being expressed by our medical colleagues ---

particularly from those with expertise and experience using antidepressant, antipsychotic, and immunosuppressant medications with the most vulnerable members of the Medicare population---that removing the protected status from these specific medication classes is inappropriate and will have harmful effects. These concerns include: (1) the need to have access to a full formulary of these medications to meet the profound individual differences in patient reactions to these medications that are encountered within a Medicare beneficiary population with multiple co-morbidities; (2) the significant difficulties many beneficiaries would encounter if required to transition from their current medications in these specific classes to those allowed in the new formulary; and (3) the difficulty many Medicare beneficiaries already encounter when attempting to understand and take advantage of CMS' beneficiary protections (e.g. the appeal's process).

Thus, the College makes the following recommendations:

- CMS should be very deliberate in their decision-making with regard to removing the current protections to these drug classes. The Agency should take the concerns expressed by our colleagues into full consideration. As part of this deliberate approach, CMS may want to consider employing an independent group of experts (e.g., physicians, other health professionals, pharmacists, health policy experts, patient advocates) to review available evidence related to this proposed change and provide recommendations to the agency.

- If and when CMS finalizes the lifting of protections to these drug classes, the College recommends that a monitoring program be implemented to assess the effects (particularly the potential adverse effects) of this action. At a minimum, this monitoring program should assess:
    - changes in overall health in these populations (e.g. changes in emergency department or hospital use)
    - changes in overall healthcare costs
    - changes in appeal process activity including number of appeals, timeliness of decisions and overall outcome of appeals

- **Enrollment Requirements for the Prescribers of Part D Covered Drugs—** CMS is proposing that a prescriber of Part D drugs must have either:

(1) An approved enrollment record in the Medicare FFS program (that is, original Medicare); **or**
(2) A valid opt-out affidavit on file with a Part A/ Part B Medicare Administrative Contractor (A/B MAC) for a prescription to be eligible for coverage under the Part D program.

This would allow CMS to ensure through the credentialing required within the enrollment process that Part D drugs are prescribed only by qualified prescribers. This proposal is part of a broader effort to minimize fraud and abuse within the Part D program. While the

College supports efforts to reduce fraud and abuse, we believe numerous other federal (e.g. DEA License requirements) and state regulations (e.g., State Medical Licensing Boards) already exist to ensure that medications are only prescribed by qualified prescribers. If there are examples of fraud despite those regulations, then these regulations should be shored up, rather than creating another bureaucratic hurdle for physicians, even if it will only apply to a small number of them.

While not directly related to this section, we encourage CMS to again consider participation in the CAQH universal credentialing application process used by many private sector healthcare systems. Having one "portal" for physicians to become credentialed for both Medicare and private sector health plans will further contribute to reducing administrative burden for physicians.

- **Permit Revocation of Medicare Enrollment for Abusive Prescribing Practices and Patterns ---** CMS is proposing, based on the results of recent research studies and recommendations from the Office of the Inspector General, to add authority to revoke a physician's or eligible professional's Medicare enrollment if:

  (1) CMS determines that he or she has a pattern or practice of prescribing Part D drugs that is abusive and represents a threat to the health and safety of Medicare beneficiaries or otherwise fails to meet Medicare requirements; or
  (2) His or her Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked; or
  (3) The applicable licensing or administrative body for any state in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs.

  This proposed expanded authority to take administrative action against physicians or other eligible professionals under the above situations, is also is part of a broader effort to minimize fraud and abuse within the Part D program.

  While the College supports this proposed expanded authority under categories (2) and (3), we oppose the expansion of such authority under category (1). We are concerned that the terms "abuse" and "threat to health and safety" are not adequately defined and that Medicare through its regulatory representatives does not have the required expertise to makes revocation determinations within this category. Rather, consistent with CMS' stated efforts to minimize fraud and abuse, ACP encourages CMS to implement systems to monitor for evidence of abusive or harmful prescribing by a provider (e.g. by using the criteria listed in the proposed rule), and subsequently provide this information, when deemed appropriate, to the relevant State Licensing Board for action. These Boards are experienced with these type of determinations, already have the authority to suspend or revoke prescribing (and practice) privileges, and provide necessary due rights protections to accused prescribers.

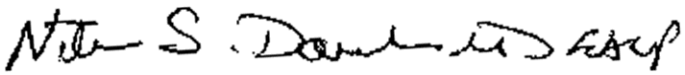
- **Broadening the Release of Part D Data ---** CMS proposes to expand the release of unencrypted prescriber, plan, and pharmacy identifiers contained in prescription drug

event (PDE) records to give researchers broader access to health care data. The College is not opposed to this expansion and further supports the continued abiding to "minimum necessary," "legitimate researcher" and "non-release for commercial purposes" policies regarding release of this information as required by law.

CMS, within this proposed rule, also specifically solicited comment on the current restriction on the release of unencrypted PDE data for commercial purposes. The College recognizes and supports the increased efforts by the Secretary and CMS to expand healthcare transparency, (e.g. the current implementation of the Open Payments (Sunshine Act) program)). Nonetheless, we remain concerned that releasing such unencrypted data for commercial purposes may have an undue and unanticipated adverse influence on physician prescribing practices and suggest that this decision be delayed at least until adequate information is developed on the effects of making this unencrypted data available to legitimate researchers (as proposed).

Please contact Neil Kirschner at nkirschner@acponline.org or 202 261-4535 if you have any questions regarding these recommendations.

Respectfully,



Nitin S. Damle MD, MS, FACP
Chair
Medical Practice and Quality Committee