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March 7, 2014

The Honorable Marilyn B. Tavenner,
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4159-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via http://www.regulations.gov.

RE: Comments on the "Enrollment Requirements for the Prescribers of Part D Covered Drugs (§ 423.120(c)(5) and (6))" & "Improver Prescribing Practices (§ 424.535(a)(13) and (14)" in the Proposed Medicare Program Contract Year 2015 Policy and Technical Changes (Docket number RIN: 0938-AR37)

Dear Administrator Tavenner:

Public Citizen – a consumer advocacy organization with more than 300,000 members and supporters nationwide – submits these comments regarding the proposed prescriber-related provisions in the proposed rule referenced above.[1]

The Centers for Medicare & Medicaid Services (CMS) is presented with a unique opportunity to develop and implement an important policy that will go a long way toward protecting Medicare beneficiaries from receiving care from incompetent or negligent prescribers. We are pleased that CMS is proposing to take steps to provide better oversight over prescribers under the Part D program. We believe the proposed rule will be instrumental in protecting Part D beneficiaries from ineligible, incompetent, and negligent prescribers. We commend CMS on embracing the majority of the recommendations made in reports from the Office of Inspector General (OIG) and others [2,3,4] that identified the vulnerability of the Part D program to abuse and fraud by risky and incompetent providers.

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[1] Department of Health and Human Service, Centers for Medicare & Medicaid Services. *42 C.F.R. 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: January 10, 2014 (Volume 79, Number 7).
[2] Department of Health and Human Services (DHHS), Office of Inspector General (OIG). *Prescribers With Questionable Patterns in Medicare Part D*. Washington, DC: DHHS OIG; 2013. Publication OEI-02-09-00603**.**
[3] Department of Health and Human Services (DHHS), Office of Inspector General (OIG). *Medicare Inappropriately Paid For Drugs Ordered By Individuals Without Prescribing Authority*. Washington, DC: DHHS OIG; 2013. Publication. OEI-02-09-00608.
[4] Tracy Weber, Charles Ornstein and Jennifer LaFleur. *Medicare Drug Program Fails to Monitor Prescribers, Putting Seniors and Disabled at Risk*, ProPublica, May 11, 2013. Web site: http://www.propublica.org/article/part-d-prescriber-checkup-mainbar. Accessed February 24, 2014.

Public Citizen's Health Research Group has been conducting and disseminating research in the area of provider (mainly physician) accountability for four decades. Our comments primarily pertain to the "Enrollment Requirements for the Prescribers of Part D Covered Drugs (§ 423.120(c)(5) and (6))" and "Improper Prescribing Practices (§ 424.535(a)(13) and (14)." Our comments are organized below by the specific areas (in italics) for which comments were requested:

(1) *We are proposing an enrollment deadline of January 1, 2015 [for providers to verify their prescribing credentials through their enrollment in the Medicare Fee for Service (FFS) program with an approved enrollment record or their submission of a valid opt-out affidavit on file with a national provider identifier at a Part A/Part B Medicare Administrative Contractor], which would provide physicians and eligible professionals with at least 6 months after the publication of a final rule to initiate and complete the Medicare enrollment process for the purpose of prescribing covered Part D drugs. We are soliciting comments regarding the effective date of this provision... (Page 1982).*

Public Citizen's Comments:

We believe the proposed 6-month enrollment period for unenrolled providers to enroll in the Medicare FFS program or to submit a valid opt-out affidavit is more than adequate for providers to be able to comply with the new rule. We believe this provision will help ensure that Part D drugs are prescribed only by qualified prescribers and should be implemented as soon as possible.

(2) *Whether we should consider requiring all pharmacies (for example, network, non-preferred, home infusion, non-retail or mail order, and out-of-network) to enroll or maintain enrollment in the Medicare FFS program in order to dispense covered Part D drugs…. Alternatively, we seek comment on whether FFS enrollment for network pharmacies is a 'best practice' in pharmacy contracting by plan sponsors and should be an integral part of sponsors' required fraud, waste and abuse programs (Page 1984).*

Public Citizen's Comments:

We agree with CMS about the imperative of requiring all types of pharmacies to enroll or maintain enrollment in the Medicare FFS program in order to dispense covered Part D drugs. We agree with CMS that this area would leverage the credentialing, identity verification, and other safeguards that are part of FFS enrollment process – allowing Part D sponsors to leverage an important program integrity tool for their networks.

(3) *[Comment on] our proposal that doctors of dental surgery or dental medicine enroll in the Medicare program in order to prescribe covered Part D drugs…(Page 1984).*

Public Citizen's Comments:

We commend CMS for proposing to require doctors of general surgery and dental medicine be enrolled in the Medicare program to be able to prescribe Part D drugs. Several studies have shown that risky dentists can cause significant harm to patients. For example, dentists accounted for 13percent of malpractice and adverse events reports in the National Practitioner Data Bank

(NPDB) during 1990-2004.[5] We strongly believe that all types of dental practitioners who would be eligible under state laws to prescribe Part D drugs should also be subject to the same requirements as physicians and other providers. Therefore, dentists should be required to enroll in Medicare to able to prescribe Part Drugs. This will help ensure that dentists with conduct and performance deficiencies are not in the position to prescribe and harm Part D beneficiaries.

(4) *Comments on our proposed additions of § 424.530(a)(11) and of § 424.535(a)(13) and (14)…. We are especially interested in receiving comments on the following issues:*
- Whether certain proposed criteria should not be used.
- Whether criteria that we did not propose should be used.
- Whether certain criteria should be given more or less weight than others.
- Whether our proposed additions of § 424.530(a)(11) and of § 424.535(a)(13) and (14) should be expanded to include pharmacy activities (Page 1987).

Public Citizen's Comments:

We applaud the above proposed provisions and agree with CMS that it is hard to define "abusive' prescribers and that it would be more appropriate to use a list of criteria in determining whether a prescriber is engaging in prescribing practices sufficient to warrant a revocation from enrollment in the Part D program. We recommend that CMS use all of the criteria identified in the proposed rule. We offer comments to bolster a few of these proposed criteria, suggest other criteria, and make a few suggestions on what criteria should be given more weight than others:

(a) Drug Enforcement Agency (DEA) certification – the proposal to expand the requirement for having valid DEA certification to all Part D prescribers (as opposed to the current practice of limiting this requirement to prescribers of controlled substances) would better protect the safety of Part D beneficiaries. The proposed rule posits using the DEA website, which contains a list of physicians, eligible professionals, and pharmacies that have had their DEA Certificate of Registration suspended or revoked since 2000: *http://www.deadiversion.usdoj.gov/crim_admin_actions/index.html*. We caution that the DEA list does not provide information on prescribers and pharmacies with reinstated certifications. We believe information on prescribers with previously revoked DEA certifications should be taken into consideration when "patterns of abusive prescribing" are assessed to determine whether practitioners should be granted prescribing privileges in Part D program. Therefore, we urge CMS to add among its proposed criteria a requirement to access historical information on prior revocations of DEA certification for questionable prescribers – this information is currently available in the NPDB from 1990 to 2013 and is updated by the Health Resources and Services Administration (HRSA) on a quarterly basis.

(b) OIG exclusion reports – leveraging OIG exclusion information in determining provider eligibility to prescribe Part D drugs is an important criterion proposed by CMS. Similar to comment (a) above, we recommend that CMS consider using the NPDB to obtain historical information on prescribers with questionable prescribing practices and to use this information when making determinations about their Part D prescribing eligibility.

[5] Shulman JD, Sutherland JN. Reports to the National Practitioner Data Bank involving dentists, 1990-2004. *The Journal of the American Dental Association.* 2006;137:523-528.

(c) In considering the use of final adverse action and malpractice payment data of providers, we recommend that CMS consider the frequency, severity, and types of disciplinary action taken by state licensing boards; the frequency, severity, and types of clinical privileges actions taken by hospitals/managed care organizations; and the number and size of malpractice payment payouts. For example, providers with multiple adverse action reports and/or frequent high malpractices payments should be scrutinized carefully and not be permitted to prescribe Part D drugs when CMS determines that it is in the best interest of the health and safety of the public. Similarly, we urge CMS to weigh the criterion of the basis for disciplinary actions against providers more heavily in cases of obvious provider misconduct, such as "incompetence," "criminal activity," "immediate threat to health or safety," "alcohol and/or other substance abuse," "fraud," "patient abuse," "sexual misconduct," and "behavioral misconduct."

(d) In addition to the proposed criteria of "revoked" or "suspended" license, we ask CMS to consider adding voluntary and involuntary surrender of clinical privileges or licensure as a criterion to determine a provider's eligibility to prescribe Part D drugs. Our research shows that many hospital and professional peer review panels and state licensing boards tend to be lenient on providers and allow them to voluntarily or involuntary surrender their clinical privileges or licenses, in lieu of revoking or suspending their licenses or clinical privileges. In fact, these voluntarily and involuntary surrenders of clinical privileges and licenses often signify a major conduct or performance issue. In addition, the majority of disciplinary actions that state licensing boards have been taking against physicians are based on consent agreements.[6] Therefore, it is imperative that CMS consider any disciplinary action(s) taken against a provider as a red flag when investigating providers for engaging in possible abusive practices.

(e) Finally, we recommend that CMS capitalize on the NPDB and collaborate with HRSA to utilize all available information on risky prescribers identified in the NPDB. The NPDB is the nation's most important source of information on adverse actions taken against health care providers.

Conclusions

The proposed rule takes substantial and important steps toward addressing prescriber-related Part D abuses. We commend CMS for recognizing the need for significant changes to the Part D program, and we urge that the Final Rule retains these changes to protect the interests of beneficiaries. We urge CMS to use all available information on prescriber behavior when making determinations about their eligibility to prescribe Part D medications.

[6] Department of Health and Human Services (DHHS), Office of Inspector General (OIG). *State Medical Boards and Medical Discipline.* Washington, DC: DHHS OIG; 1990. Publication oei-01-89-00560.

Thank you for the opportunity to comment on this important rule.

Sincerely,

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