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Public Citizen Comments on National Practitioner Data Bank (NPDB) NPRM, Feb. 15, 2012, Federal Register/Vol. 77, No. 31, pages 9138-9161

A. Reporting By Medicare Quality Improvement Organizations (QIOs)

B. Definition of "Negative action or finding by a Federal or State licensing or certification authority…" [60.3 (c)]

A. Medicare QIOs Should Be Required to Report

Legal Analysis/Comments

As proposed, Section 60.3 (definitions) will define "peer review organization" to "exclude utilization and quality control peer review organizations described in Part B of Title XI of the Social Security Act (referred to as QIOs)," 77 Fed. Reg. 9138, 9146 (Feb. 15, 2012). We urge the Department of Health and Human Services (HHS) to adopt a definition of "peer review organization" that *includes* QIOs because excluding them is contrary to the statute these proposed regulations are intended to implement.

In 42 U.S.C. § 1396r-2(a)(1), Congress required states to have a system of reporting various enumerated adverse actions against health care practitioners or entities by "any authority of the State (or of a political subdivision thereof) responsible for the licensing of health care practitioners (or *any peer review organization* or private accreditation entity reviewing the services provided by health care practitioners) or entities" (emphasis added). The phrase "any peer review organization" makes clear that the state's reporting system must include adverse actions taken by a "peer review organization" of "any" kind, without limitation. *Ali v. Federal Bureau of Prisons*, 552 U.S. 214, 220 (2008): "Congress' use of 'any' to modify 'other law enforcement officer' is most naturally read to mean law enforcement officers of whatever kind" (footnote omitted); *United States v. Gonzales*, 520 U.S. 1, 5 (1997): "Read naturally, the word 'any' has an expansive meaning, that is, 'one or some indiscriminately of whatever kind'"

(quoting Webster's Third New International Dictionary 97 [1976]). The statutory scheme also indicates that a "QIO" is a kind of "peer review organization": specifically, section 1396r-2 refers to "utilization and quality control *peer review organizations* described in part B of title XI," 42 U.S.C. § 1396r-2(b)(4) (emphasis added), and part B of title XI in turn sets forth the requirements for "quality improvement organizations," *see* 42 U.S.C. § 1320c. Indeed, the proposed regulation itself acknowledges that a QIO is a type of "peer review organization," 77 Fed. Reg. at 9146 (noting that "utilization and quality control peer review organizations described in Part B of Title XI of the Social Security Act" are "referred to as QIOs").

Buttressing this interpretation of the statute as designed to include QIOs is the legislative history of Title XI, Part B. When the reporting requirement, section 1396r-2, was passed in 1987, *see* Pub. L. 100-93, its reference to "any peer review organization" indisputably included QIOs, because at that time, the Title XI, Part B used the phrase "utilization and quality control *peer review organizations*" to refer to what are now called QIOs. *See* 42 U.S.C. 1320c (1987) (emphasis added), *enacted by* Pub. L. 97-248, § 143 (Sep. 3, 1982), *amended by* Pub. L. 112-40, § 261(a)(2)(C) (Oct. 21, 2011): (amending Title XI, Part B "by striking 'utilization and quality control peer review' and 'peer review' each place it appears before 'organization' or 'organizations' and inserting 'quality improvement'").[1]

For these reasons, a regulatory definition of "peer review organization" that excludes QIOs is irreconcilable with the text of the statute. HHS regulations should not adopt any language that excludes QIOs from the definition of "peer review organization."

Policy Analysis/Comments

Public Citizen disagrees with the HHS rationale for not requiring QIO reporting to the NPDB (see Federal Register, July 28, 2010, Section 1921 Final Rule, page 4666, Section 4, and Peer Review Organizations).

According to HHS "…the reporting of QIO sanction recommendations to the NPDB will significantly interfere with the critical mission of the QIO program, which focuses on maintaining collaborative relationships with providers and practitioners to improve the quality of health care services delivered to Medicare beneficiaries…"

If this "rationale" or logic was applied to self-regulation by hospital peer review committees or state medical boards or private accreditation organizations or professional associations, there

[1] Predating the statutory change, HHS has been using the term "QIO" since 2002. *See Public Citizen, Inc. v. U.S. Dep't of Health & Human Servs.*, 332 F.3d 654, 655 n.1 (D.C. Cir. 2003) (citing 67 Fed. Reg. 36,539 (May 24, 2002)).

would be no reporting at all, and thus the NPDB would be left with just medical malpractice reports.

All physician peer review activities, whether by hospital peer review committees, state medical boards or others, have within the process itself the tension of assuring patient safety while at the same time providing the practitioner with due process and an opportunity for improvement. To state, as HHS has done, that QIO reporting would interfere with this process is to put patients (i.e., the public) at risk as well as to absolve QIOs from acting responsibly in reporting substandard care.

Also, as long ago as 1993, the Centers for Medicare and Medicaid Services (then the Health Care Financing Administration) was advised by the Office of the Inspector General (OIG) of HHS (http://oig.hhs.gov/oei/reports/oei-01-92-00530.pdf) to have QIOs report questionable physicians to state medical boards. Specifically, the OIG noted, "The PROs identify physicians responsible for serious quality-of-care problems but they seldom inform State medical boards about these physicians. In prior reports, we have expressed concern that this lack of information sharing inhibits the boards' effectiveness in protecting Medicare and Medicaid beneficiaries…"[2]

In response to the report, the Public Health Service at HHS wrote, "Requiring that a report be filed with the state medical board after a medical review is consistent with requirements for reporting other types of peer review activity to the National Practitioner Data Bank."

B. The NPRM Should Provide for a More Detailed Definition of Negative Action or Finding

According to the NPRM, "To-date, we have allowed reporting entities to apply their own specific definition of negative action or finding. " [60.3 (c) 2]

The NPRM notes that an effort has been made to provide more specific guidance on what constitutes a "negative action or finding." However, the NPRM does not go far enough to ensure that the NPDB receives all notifications (i.e., reports) of adverse actions taken by reporters, particularly state medical boards. According to the most recent NPDB Annual Report, for 2009, state medical licensing board reports constituted almost 20 percent of all reports in the NPDB and 55 percent of all adverse action reports.

[2] Office of Inspector General, U.S. Department of Health & Human Services, Peer Review Organizations and State Medical Boards: A Vital Link, 1993, p. I, http://oig.hhs.gov/oei/reports/oei-01-92-00530.pdf

The lack of a more detailed definition of “negative action or finding” compromises the integrity of the NPDB, since it provides the potential for under-reporting, which undermines congressional intent regarding the establishment of a national data base.

As a result of inconsistent definitions among various reporters, NPDB queriers will be adversely impacted because they will not know whether the NPDB is providing complete information. For instance, if an NPDB querier searches for a practitioner from another state who is applying for clinical privileges in the querier’s state, the fact that the practitioner has not been reported offers little assurance that no negative actions or findings have occurred. Rather, it is possible that an incident that the querier would consider a negative action or finding did occur but was not reported because the practitioner’s state did not consider it a negative action or finding under a narrower definition than the querier would have used.

Furthermore, both reporting entities and physicians are harmed by the lack of regulatory guidance on what to report. The result of an ambiguous definition is inconsistent reporting. Practitioners may be treated unfairly because of the lack of a consistent definition. For example, a practitioner might be reported by the licensing agency of one state for precisely the same action or finding that would not be reported by another state.

Assuming HHS recognizes the wisdom of providing a definition, the next question is what the definition should be. We believe that a common sense, nontechnical definition would provide the greatest clarity and certainty for all concerned. Specifically, we would define "negative action or finding" as "any action or finding which in any way restricts a subject's ability to practice or engage in business or which a reasonable person would interpret as reflecting criticism in any way on the subject even if the subject's ability to practice or engage in business is not affected. This includes reprimands, letters of concern, consent orders, settlement agreements and any other similar item regardless of what it is called."

The intent of our proposed definition is that if an uninvolved member of the public would perceive the action or finding as reflecting poorly on the subject, then the action or finding is required to be reported. There should be no "consent orders,” letters of concern or reprimand, or other similar actions regardless of what they are called, that are not reported to the Data Bank.

A report by the inspector general of HHS underlines the need for a better regulatory definition of negative action or finding. According to the inspector general (*see* http://oig.hhs.gov/oei/reports/oei-01-89-00560.pdf), a majority of disciplinary actions that state boards take against physicians are based on consent orders. However, there is inconsistency amongst state medical boards regarding how boards handle the disclosure of consent orders to the public or the NPDB.

Public Citizen has provided to NPDB staff copies of consent orders in which a board required physicians to be supervised or monitored because of performance concerns. Unfortunately, health care organizations that queried the NPDB would not have known about the medical board's actions because as a condition of the consent orders, the medical board agreed not to report to the NPDB. The medical board also classified their actions as "non disciplinary." Yet, clearly the underlying performance concerns would be of interest to NPDB queriers. Under a more reasonable definition such as we have suggested, notice of the restrictions on such physicians' practices would be available to health care entities and organizations that query the NPDB.

As far back as the 1980s, the inspector general expressed concern at the dramatic increase in consent orders:

> "The majority of disciplinary actions that State boards have been taking against physicians are based on consent agreements.
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> "The evidence on this point is compelling. In our survey encompassing disciplinary actions taken in 1988 in eight randomly selected States, 57 percent of the actions were based on consent (or as they are often called "stipulated") agreements. Similarly, in each of our four case study States, a clear majority of actions have been resolved in this manner in recent years.
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> "Trend data concerning this issue are not usually available in the States, but there are strong signs that the proportion of cases being resolved through consent agreements has been rising sharply. Whereas only 21 States had the authority to settle cases in this manner in 1986, 41 did by 1989. And board officials and reports suggest that the boards have been quite active in taking advantage of this authority. In Connecticut, for instance, the proportion of cases decided through consent agreements rose from 69 percent in 1986 to 72 percent in 1987 to 89 percent in 1988. In Texas, the rise during the same period was from 76 percent to 77 percent to 89 percent. In 1989, the increase continued, reaching 95 percent."[3]

And the inspector general recognized the danger that such dispositions pose to public health and safely and to the licensing process — concerns that are no less valid today:

> "[A]s the proportion of cases so settled exceeds 50 percent and, indeed, nears 100 percent in some places, one wonders if the "appropriate" board action is always being taken-if the

[3] Office of Inspector General, U.S. Department of Health & Human Services, State Medical Boards and Medical Discipline, August 1990, p. 14, http://oig.hhs.gov/oei/reports/oei-01-89-00560.pdf

pressure to settle might not be leading some boards in some cases to act more leniently than the violation would warrant.

"One also wonders about the extent to which such settlements, when they represent the initial disciplinary action against a physician, will impede or complicate actions against that same physician by other States in which he or she is licensed. Without a prior action involving a full evidentiary hearing, another jurisdiction may face the prospect of conducting additional investigative work of its own."[4]

Conclusion

The Institute of Medicine, in its 2006 report on Medicare QIOs, noted, "[T]he committee concluded that the QIO program has the potential to help meet the crucial need of improving the quality of health care…"[5]

As long as QIOs are not required to report questionable practitioners to the NPDB, QIO peer review actions will remain in the shadows, shielded from hospitals, health maintenance organizations and other health care organizations that rely on NPDB data to make informed credentialing and employment decisions.

In addition, as long as HHS continues to use an inadequate and outdated definition of "negative action or finding," the value of NPDB data is seriously compromised by inconsistent reporting.

[4] Ibid, p. 14
[5] Institute of Medicine, Medicare's Quality Improvement Organization Program, 2006, p. 5