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March 13, 2017

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
ATTN: CMS-10265
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Mandatory Insurer Reporting Requirements of Section 111 of the Medicare, Medicaid, and SCHIP Act of 2007 [CMS-10265]**

Dear Sir or Madam:

We are pleased to provide our comments in response to the Centers for Medicare & Medicaid Services (CMS) request for comment entitled *Agency Information Collection Activities: Proposed Collection; Mandatory Insurer Reporting Requirements of Section 111 of the Medicare, Medicaid, and SCHIP Act of 2007*.

Interest of PIAA

PIAA is the insurance industry trade association that represents a full range of entities doing business in the MPL/HPL arena, including insurance companies, risk retention groups, captives, trusts, and other entities. PIAA members include MPL/HPL enterprises owned and/or operated by physicians, hospitals, health systems, dentists and oral maxillofacial surgeons, podiatrists, chiropractors, and healthcare providers such as nurse practitioners, nurse midwives, CRNAs, and many others, as well as insurance carriers with a substantial commitment to the MPL/HPL line. PIAA members insure more than two-thirds of America's physicians in private practice, as well as dentists, nurses and nurse practitioners, and other healthcare providers, and they insure more than 2,500 hospitals nationwide.

Comments

PIAA supports CMS' efforts to monitor the documentation burden of Section 111 of the "Medicare, Medicaid, and SCHIP Act of 2007" ("Section 111") reporting, and to guarantee that such obligation is no more onerous than required by statute. In that vein, we urge CMS to revise its sub-regulatory guidance as provided in "Non-Group Health Plan (NGHP) User Guide 5.2" (Ch. III §6.5, p.6-26) to make clear that Section 111 reporting is not required absent a claim.

Our concerns arise from questions we have received from our membership regarding voluntary informal patient assistance programs. Such programs provide patients who experience an unexpected health outcome with timely financial assistance without an assessment of fault, which is the touchstone of liability under a professional liability insurance policy. Such programs also address issues that may not rise to the level of a successful claim, such as a known complication, and can be a desirable avenue to

address unexpected health outcomes with patients. They may also reimburse patients for expenses that would not be covered under Medicare. Our understanding is that, in certain circumstances, CMS views such programs as “risk management tools,” and requires reporting under such programs even without the presence of a claim or claimant.

We believe that the statutory authorization and requirements of Section 111 do not permit CMS to require reporting for payments under such informal assistance programs. Further, it appears that CMS’ stance on this point countervails clear guidance issued by the National Practitioner Data Bank (NPDB) on similar programs. Lastly, we note that, pursuant to the Agency’s efforts to reduce regulatory burden, this is an area ripe for review. We provide more detailed comment on each of these points below for CMS’ consideration, as well as recommended revisions to the NGHP User Guide 5.2 that would effectively address our concerns.

I. Patient Benefit

Informal assistance programs are built on the recognition of patients’ immediate needs and the provision of limited financial assistance in the event of an unexpected health outcome. Such programs are designed to be a tool to help preserve the physician-patient relationship by allowing the physician to have tangible means to assist a patient with the effect of an unexpected health outcome. By preserving the physician-patient relationship, patients often choose not to pursue adversarial litigation which may take years to resolve and the physician may continue to care for the patient. Deeming all informal assistance programs as merely “risk management tools” misunderstands and trivializes the true nature and benefit of these programs. Specifically, we have observed that such programs promote and enable open physician-patient communication and create a rapport within which patients are more willing to face an unanticipated outcome. Informal assistance programs also recognize and seek to address the financial burdens that may follow an unexpected outcome (again, without regard to fault or negligence). These programs are beneficial to patients, including Medicare beneficiaries. Qualitative data supports this premise.¹

II. Statutory Authority

While Section 111 requires mandatory reporting of certain settlements and judgments paid by medical/healthcare professional liability insurers and other entities to Medicare beneficiaries, Section 111 does not grant CMS the authority to require reporting when there is no claim or claimant. Section 111 specifically provides:

[A]n applicable plan shall-- (i) determine whether a claimant (including an individual whose claim is unresolved) is entitled to benefits under the program under this subchapter on any basis; and (ii) if the claimant is determined to be so entitled, submit the information described in subparagraph (B) with respect to the claimant to the Secretary in a form and manner (including frequency) specified by the Secretary.

¹ Gallagher T, Studdert D, Levinson W. Disclosing Harmful Medical Errors to Patients. *N Engl J Med.* 2007;356:2713-2719; Gallagher T, Mello M. Malpractice Reform – Opportunities for Leadership by Health Care Institutions and Liability Insurers. *N Engl J Med.* 2007;362:1353-1356; Duclos C, Eichler M, Taylor L, et al. Patient perspectives of patient-provider communication after adverse events. *Int J Quality Health Care.* 2005;17:479-486.

[T]he term “claimant” includes-- (i) an individual filing a claim directly against the applicable plan; and (ii) an individual filing a claim against an individual or entity insured or covered by the applicable plan. 42 U.S.C. § 1395y(b)(8)(A), (D).

The statute clearly limits the reporting obligation to cases where an individual, or claimant, has filed a claim. In spite of this clear Congressional directive, CMS’ sub-regulatory guidance provides that reporting may be required in instances where no claim has been filed and there is no demonstrated responsibility for payment. Specifically, CMS’ guidance at Ch. III §6.5, p. 6-26 of the NGHP User Guide 5.2 suggests that, in certain situations, even though no claim exists, an entity may be required to report.

III. Countervailing guidance

Reporting in instances where there is no claim is inconsistent with the guidance provided by the National Practitioner Data Bank (NPDB). It is our understanding that payments made as part of an informal assistance program are not subject to reporting under the NPDB (as long as the patient has not made a written demand or claim). Specifically, the NPDB requires medical/healthcare professional liability payer reporting only in instances of medical/healthcare professional liability payments resulting from a written claim or judgment. In fact, the NPDB Guidebook offers an illustrative example in a Q&A format:

Q. Following an unsuccessful course of treatment, a patient and a practitioner enter into a State-sponsored voluntary series of discussions in an attempt to settle their disagreement before resorting to litigation. The discussions lead to the practitioner's insurance company making a money payment to the patient to settle the dispute. Should this money payment be reported to the NPDB?

A. It depends. If, during the course of discussions, the patient made a written complaint or written claim demanding a monetary payment for damages, the payment must be reported. If the complaint or claim for damages was never put in writing, the payment is not reportable.

To streamline entity reporting, we submit that it would be helpful for the Section 111 guidance and the NPDB guidance to be in harmony; if the presence of a written claim is required for purposes of NPDB reporting compliance, it would make sense for it to be required also for compliance with Section 111.

IV. Reducing regulatory burden

It is our understanding that the Administration is currently identifying areas for regulatory relief subject to the “Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs” issued on January 20, 2017. We believe that CMS’ ongoing efforts to monitor and, when appropriate, reduce the documentation burden of its regulations is a valuable activity toward this goal.

Modifications to reduce the burden of Section 111 reporting, particularly in areas where the Agency could base such modifications on statutory limitations and streamlining with other Agency programs and state guidance, would be valuable to CMS and stakeholders. We are happy to expand upon any portion of this comment letter or the legal analyses therein if that would be helpful to CMS as it continues to examine its programs and areas for regulatory burden reduction.

V. Recommended revisions

To ensure that Section 111 reporting is limited to instances where there is a claim and to address our other concerns above, we suggest the following revision to the (NGHP) User Guide Version 5.2:

“In instances where any other entity has reduced its charges, written off some portion of a charge or provided other property of value to a Medicare beneficiary as such a risk management tool when there is evidence, ~~or a reasonable expectation,~~ that the individual has made a written complaint or a written demand ~~has sought or may seek medical treatment~~ as a consequence of the underlying incident giving rise to the risk, the entity shall report the reduction, write-off or property of value provided as a TPOC from liability insurance (including self-insurance). If the amount of the reduction, write-off or property of value provided is less than TPOC reporting threshold, it need not be reported under Section 111.” (User Guide, Ch. III §6.5, p.6-26)

We believe that these minimal edits would facilitate valuable dispute resolution for patients, appropriately tailor the requirement to the statutory authorization granted by Section 111, streamline the Act’s requirements with those of the NPDB and states, and achieve CMS’ goal to reduce regulatory burden.

We appreciate the opportunity to provide input regarding Section 111 requirements. Please do not hesitate to contact me should you need any further information.

Sincerely,

A handwritten signature in blue ink that reads "B. Atchinson". The signature is fluid and cursive, with a large initial "B" and a clear "Atchinson" following.

Brian Atchinson
President and CEO