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Donald Berwick, MD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health & Human Services  
Attention: CMS-6028  
Submitted electronically on November 16, 2010

**Re: CMS-6028; Proposed Regulations on Medicare, Medicaid, Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers; 75 *Federal Register* 58204 (September 23, 2010)**

Dear Dr. Berwick:

The Medical Society of New Jersey (MSNJ) represents 9,000 physicians practicing in the state of New Jersey. MSNJ appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rules concerning Medicare, Medicaid and the Children's Health Insurance Programs on additional requirements to implement the Affordable Care Act (ACA).

MSNJ applauds the efforts of CMS to root-out and prosecute individuals who defraud the Medicare, Medicaid, and CHIP programs. There are precious few healthcare dollars and they should be spent on medical treatment, not to line the pockets of criminals and those who would game the system.

#### **The Proposed Fraud Standard**

While increased enforcement may be warranted, MSNJ believes that current law and regulations, when effectively enforced, provide a sound basis for the Government to fight fraud. This is evidenced in the recent sting operations by the newly created Healthcare Fraud Prevention and Enforcement Action Team (HEAT), whose work we endorse, where physicians and others scam the Government programs, patients, and taxpayers. While we recognize that ACA mandated authority may be necessary to protect the funds dedicated to medical treatment of seniors, children, and the indigent, we are concerned that the proposed rules will allow too much discretion for regulators and enforcement officials, particularly when implemented against physicians who may have good faith disagreements concerning clinical appropriateness, documentation, coding, and billing disputes, resulting in alleged overpayments.

MSNJ urges CMS to carefully consider the experience in New Jersey with respect to “alleged overpayments” by private payers before lowering the standard for fraud. We will assist CMS by providing specific examples of insurers alleging fraud to extract huge sums of money from physicians who are practicing medicine in good faith, but who are targeted based on data-mining of claims. Their billing and coding practices are alleged to be improper or fraudulent by the Special Investigation Units of private insurers. When the alleged overpayments are challenged by the physicians, the insurer often agrees that the coding/billing was actually correct for the vast majority of the alleged overpayments and settles for a fraction of the alleged total overpayment.

The pressure for physicians to settle these allegations for a fraction of the alleged amount is overwhelming, if only to remove the taint of the fraud allegation. The settlement option may be necessary simply to keep the practice in business since payment of the total alleged overpayment would result in serious cash-flow problems. Even when settled, the insurer will place the practice in pre-payment review of all similar claims, resulting in slow-to-no payment, worsening the cash-flow issue. This is an abuse by the payers with overwhelming power; they appear to be inviting a negotiation to settle, rather than rooting out fraud. Yet, this is occurring even where the standard for fraud is higher than that contained in these proposed regulations.

MSNJ is concerned that the proposed standard “credible evidence of fraud” that could result in a payment suspension is far lower than that currently in effect under New Jersey law with respect to recoupment by commercial health insurers. In New Jersey, private healthcare insurers are permitted to exceed the statutory time restriction on recouping overpayments when there is evidence of claims “submitted fraudulently,” or a “pattern of inappropriate billing.” See NJSA 17B:26-9.1 (10). They are permitted to use extrapolation to exponentially increase the amount of the alleged overpayment when there is “clear evidence of fraud” and the matter has been investigated internally and referred to the state’s office of insurance fraud. See NJSA 17B:26-9.1(10)(d). Yet we see requests for overpayments for alleged fraud that are merely trumped up efforts to recoup money for valid claims submissions and payments. Fraud is a “state of mind” crime which requires intent. Fraud cannot be inferred from a pattern of coding and billing that is subject to good faith differences of interpretation.

The unfettered discretion allowed under the New Jersey commercial standard (clear evidence) for fraud in the context of alleged overpayments is likely to occur under the proposed standard here. If CMS adopts and implements the proposed standard (credible evidence) in a fashion similar to or more aggressive than the private insurers in New Jersey, MSNJ believes that there will be a sudden and significant access issue for our seniors, children, and the indigent.

Physicians treat Medicare, Medicaid, and CHIP patients at a significantly discounted fee. There is simply a limit to how much a physician will put his or her reputation and practice at risk of being accused of fraud over a good faith documentation, coding, or billing dispute. When a low standard for fraud, data mining, and a billing or coding practice subject to a good faith dispute, may result in unwarranted accusations of fraud by overzealous regulators or enforcement officials, law-abiding physicians will manage their risk by not participating in the Government programs.

Participation in Government programs is already on the wane in New Jersey. Data from Highmark Medicare Services, New Jersey's Medicare Administrative Contractor, demonstrates that physicians are opting out of the Medicare program. In fact, the number of physicians opting-out of the Medicare program has increased dramatically over the past three years. Similarly, there is a shortage of physicians who will treat Medicaid patients in New Jersey because the state has the lowest reimbursement rates in the country which do not adequately cover the cost of treatment.

***MSNJ urges CMS to carefully balance the potential negative impact on access to care against the actual incidence of fraud with respect to coding, billing, and payment policy disputes.*** If CMS uses a cannonball to kill a flea, the collateral damage will be physician flight from the Government programs and an access to care issue for seniors, children, and the indigent. CMS already has an arsenal of tools at its disposal to address overpayment issues. The ability to simply deny payment, conduct prepayment review, and the overpayment recovery process adequately protect the Medicare fund. There is no evidence that a lower standard of fraud is needed in the current program to enforce against those who are engaged in fraudulent activity. Therefore, CMS should clarify that a "credible allegation of fraud" under the ACA is consistent with the longstanding standard of proof, "reliable information that fraud or willful misrepresentation exists."

Should CMS determine that a lower evidentiary threshold is required, then cases involving disputes about clinical decision making, documentation issues, coding and billing disputes should allow for a rebuttable presumption in favor of the physician. Clearly, a pattern of practice is not tantamount to fraud as physicians typically use care paths and other decision support tools to assist their clinical practice.

### **The Proposed Payment Suspension**

The proposed regulations would allow payment suspensions for 180 days which could be renewed in increments of 180 days where there is credible evidence of fraud. There are a number of exceptions, including situations where: a suspension might signal the pending investigation and cause the perpetrator to close shop; a patient's health may be harmed; there is an access to care issue.

MSNJ believes that the proposed 180-day suspension of payment is far too long for situations where there is either no clear evidence of fraud or no risk of "flight." We have assisted many members whose billing rights under Medicare have been interrupted or revoked due to paperwork issues or the implementation of new program initiatives (e.g., NPI, PECOS, re-enrollment). These physicians could simply not stay in practice with a 180-day suspension of payment. Thankfully, Highmark Medicare Services has worked with us to help reinstate and pay these members as quickly as possible. Nevertheless, the members had to use personal funds, lines of credit, or other sources of credit in order to keep their doors open to treat their patients. Clearly, actions that will cause the closure of the practices of law-abiding physicians will interrupt patient care not just for Medicare patients, but for all patients of the practice. A 180-day suspension is tantamount to a termination without due process.

We encourage CMS to develop an exception for alleged overpayment situations where the physician has a record of participation, compliance, and credibility with the

MAC. Unless there is both a prospect of “flight” and clear evidence of fraud, the payment suspension route should not be used. We assume that CMS’s intent is that payment suspension be rarely used, but the low and ill-defined standard of fraud is worrisome since an overzealous regulator or enforcer could abuse this discretionary standard.

A payment suspension may be reversed when there is a “resolution of an investigation.” The proposed rule would define such a resolution to be termination of a legal action by settlement, judgment, or dismissal, or when the case is closed or dropped because of insufficient evidence. 42 CFR 405.370. MSNJ believes that this definition is far too rigid. Payment suspensions should only occur where there is an active, on-going investigation. If an investigation is not being actively pursued, then the suspension should be reversed. In any case of payment suspension, MSNJ urges that the suspension be tailored to the specific treatment or procedure at issue.

### **Risk-Based Screening & Tiers**

MSNJ strongly supports the proposal to assign physicians to Tier I, which is designated as the lowest risk. It is well documented that the vast majority of healthcare fraud is not perpetrated by physicians. Physicians are already subject to rigorous oversight and state licensure requirements. We strongly oppose adjustment from Tier I to a higher risk tier without notice and an opportunity to be heard. We oppose “geographical circumstances” as a reason for adjusting from one risk category to another. This would deny all physicians in the specified geographic area due process and could jeopardize the health of patients in the area.

MSNJ objects to placement of physicians who provide their own patients with durable medical equipment (DME) in a higher risk category. These physicians are already subject to the Stark Law and a number of regulations in order to provide durable medical equipment to their patients. Placing these physicians in a higher risk tier will be a disincentive to these office-based physicians to continue offering DME. Physicians who provide DME improve the quality of care and may actually decrease costs. For these reasons, the proposal should include an exception for physician office-based DME.

### **Enrollment and Re-Enrollment Fees**

Organized medicine lobbied Congress not to impose an enrollment fee on physicians as a cost to participate in the Medicare program. Physicians should not have to pay a fee to be vetted for participation in the Medicare program. These costs should be a program cost borne by the population at large, not the personal cost of a physician who treats our senior and indigent populations. **Congress decided not to require a physician enrollment fee.**

It is not clear whether the proposed regulation would require a re-enrollment fee as early as March of 2011 for those renewing their enrollment on a mandated five-year cycle. Any attempt to make physicians pay for the enrollment process defies the intent of Congress. There should be no physician enrollment, reenrollment, or vetting fees under Medicare, Medicaid, or the CHIP programs. To impose such fees ignores the intent of Congress and shifts a societal cost to physicians. In any event, physicians who treat Medicare, Medicaid, and CHIP patients should never be required to pay an enrollment or re-enrollment fee or be required to be vetted in each program. Moreover, if the

Government wishes to institute termination reciprocity between the three programs then it is only fair that vetting in a single program be honored by the others.

MSNJ is concerned that physicians who offer office-based DME may be subject to the \$500 enrollment fee because they may be deemed to be "institutional providers" under the proposal. This is beyond the scope of the authorizing statute and would frustrate congressional intent. For the reasons stated above, there is no need to heighten the screening process for physicians who offer office-based DME.

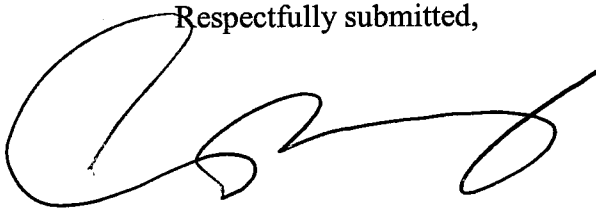
#### **Termination "Reciprocity"**

The proposed rule mandates reciprocal terminations among the three Government programs. We appreciate the Government's concern that a provider who has been terminated for cause from one state's program should not be allowed to set-up shop in another state and that there would be heightened concern about a provider who has been terminated from one program continuing enrollment in another. If, however, there is to be such reciprocity it is imperative that the termination have been for cause. As discussed above, physicians sometimes get caught in a paperwork snafu and have their billing rights terminated. These are often situations where the Government is instituting a new program and the physician is without fault. It would be patently unfair to allow a termination due to a paperwork snafu result in terminations in other Government programs and, possibly, across state lines. **Reciprocal termination must be limited to revocations of privileges due to fraud and where the physician has exhausted all possible appeal rights.**

#### **Compliance Plans**

CMS seeks advice on compliance plans that will be required by the Affordable Care Act for physicians who treat Medicare, Medicaid or CHIP patients. The Act requires the plans as a condition of enrollment. MSNJ is concerned about the undue burden this may place on small practices that do not treat a significant patient population in any one or a combination of the three programs. It is imperative that practices not be required to adopt and implement three separate plans. In addition, there should be a threshold amount of reimbursement revenue before the compliance plan requirement is mandatory. We agree that further rulemaking is necessary to establish a framework for compliance that is cost-effective.

Respectfully submitted,



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Medical Society of New Jersey