



December 12, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: OIG-405-P
P.O. Box 8010
Baltimore, MD 21244-8010

Proposed Regulation at 42 CFR Part 1001

Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute.

To whom it may concern:

The Disease Management Association of America (DMAA) appreciates the opportunity to provide comments on the proposed rule to establish new exceptions to the Federal anti-kickback statute under section 1128B(b) of the Social Security Act. DMAA strongly supports the Administration's goal to encourage widespread adoption of health information technology for the purpose of improving the quality and efficiency of health care.

DMAA

DMAA is a non-profit voluntary membership association representing all stake-holders in the disease management industry through public and private advocacy targeting the healthcare industry, government agencies, employers, and the general public in an effort to educate them on the important role disease management and care coordination programs play in improving healthcare quality and outcomes for persons with chronic conditions.

DMAA's more than 140 members include disease management organizations, health plans, employers, physician groups, hospitals, disease management support service providers, pharmacy benefit managers, pharmaceutical manufacturers, and disease management consultants. DMAA also has over 40 individual members, including individual health care professionals, academicians and other industry thought leaders, who join DMAA to access industry information and to participate in industry advocacy efforts.

Disease management is a system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant. *Disease management supports the physician or practitioner/patient relationship and plan of care, emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies, and evaluates clinical, humanistic, and economic outcomes on an on-going basis with the goal of improving overall health.* DMAA promotes population health improvement through disease and care management by: standardizing definitions and outcomes measures; promoting high quality standards for disease management and care coordination programs; and identifying and sharing best practices of program components.

General Comments

DMAA supports the purpose of Section 1128 of the Social Security Act to provide criminal penalties for individuals or entities that knowingly induce or reward the referral of business reimbursable under Federal health care programs. The proposed rule addressed in these comments would create exceptions in the anti-kickback statute to allow hospitals and other entities to donate information technology to physicians.

The disease management industry and discipline are rooted in the notion that systemic improvements in management of information are crucial to improving the quality of health care for patients with chronic disease and decreasing costs of their care. The U.S. Congress, in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and The Department of Health and Human Services have both recognized this need for improvement in the interoperability, availability and deployment of healthcare information technology.

DMAA commends CMS and the Administration for seeking to encourage the adoption of these technologies. However, our members are concerned that the proposed rule does not advance the key objects of interoperability and may ultimately inhibit the widespread adoption of health information technology by imposing severe restrictions on both permissible donors and permitted technologies.

Specific Comments

1) Electronic Prescribing Exception: Section 1128B(b)(3)(E):

“Used Solely”: The proposed rule requires that donated items and services must be “necessary and used solely” to send and receive electronic prescription drug information. CMS is concerned that physicians might intentionally divest themselves of functionally or technically equivalent items and services they already possess to shift the cost to donating entities.

However, CMS proposes to use its regulatory authority under section 1877 (b)(4) to create an additional exception to protect the provision of technology that is used for more than one function, so long as a substantial use of the items and services is to receive and transmit e-prescribing information.

DMAA Recommendation: DMAA commends CMS for its recognition that most users will prefer a single, multi-functional device, rather than many single-use devices. DMAA is concerned, however, that CMS seeks to qualify such multi-functional devices by requiring that they be “substantially” devoted to e-prescribing technologies. DMAA members believe that devices capable of e-prescribing technology, in addition to other functionalities, should be protected by this exception.

As such, HHS should use its discretionary authority to provide an exception for multi-functional technologies, provided that at least one of the functions of that technology is to receive and transmit e-prescribing transactions. DMAA believes that such an exception will further stimulate adoption of health information technology, including electronic health records.

2) Donors and Recipients Protected by the Proposed Safe Harbor

Permissible Donors: The proposed rule identifies specific entities that may be exempt from providing items and services without violating the underlying Stark regulations. They are limited to: 1) hospitals and their medical staffs; 2) group practices and their physician members; 3) prescription drug plan sponsors to their physicians; and 4) Medicare Advantage organizations to their physicians. In the preamble, CMS states that it does “not believe that providers and suppliers of ancillary services, such as laboratories, are well positioned to advance the goal of widespread use of interoperable electronic health records for patients, nor would they have the same interest in doing so.”

DMAA Recommendation: Organizations providing population health management services have an interest in promoting and advancing the widespread use of interoperable electronic health records for patients and should be included in the list of permissible donors. Disease and care management programs and services provide coordinated healthcare interventions and communications for patients with chronic conditions in support of the physician/provider-patient relationship. Physician/provider electronic communication promotes the coordinated care efforts with exchange of treatment plans, patient education and compliance/outcomes measures. These programs and services utilize advanced HIT technologies and the widespread use of electronic health records would further improve the care of populations with chronic conditions.

As such, DMAA recommends that HHS use its discretionary authority to promote the advancement and adoption of electronic health records to assist in the care of these chronic populations by exempting entities such as disease and care management organizations.

We appreciate the opportunity to provide these comments, and look forward to working with the Administration to promote the rapid adoption of health information technology for the benefit of all participants in the health care delivery system. Please do not hesitate to contact me if you have any questions about DMAA’s comments on these proposed regulations.

Sincerely,

Tracey Moorhead
Executive Director