

Request for Emergency Clearance of the Paperwork Reduction Act for Collection of Information Requirements Related to Agreements Executed by Parties Intending to Comply with New Exceptions to the Physician Self-referral Law found at 42 C.F.R. §§411.357(v) and (w) Regarding Arrangements Involving the Donation of Electronic Prescribing and Electronic Health Records Technology.

The Centers for Medicare & Medicaid Services (CMS) is requesting that a Paperwork Reduction Act (PRA) package for collection of information required under two new exceptions to section 1877 of the Social Security Act (Act) be processed under the emergency clearance process. The approval of this collection process is essential to protect the Medicare program and its beneficiaries against fraud and abuse. In addition, it emergency approval is essential to permit members of the health care industry to immediately reap the benefits of this important regulation. Once the new exceptions are effective, entities that furnish certain designated health services to Medicare beneficiaries will be permitted to assist physicians with the implementation of electronic prescribing and electronic health records technology. The benefits of this technology include reducing medical errors, coordinating care, improving efficiency, and decreasing health care costs by eliminating unnecessary and/or duplicative diagnostic services.

Background

As required by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Department of Health and Human Services (Department) plans to issue a final rule (CMS-1303-F) that creates an exception to the physician self-referral prohibition in section 1877 of the Act for certain arrangements in which a physician receives compensation in the form of items or services (not including cash or cash equivalents) (“nonmonetary remuneration”) that is necessary and used solely to receive and transmit electronic prescription information. In addition, using its separate legal authority under section 1877(b)(4) of the Act, the Department is promulgating a separate regulatory exception for certain arrangements involving the provision of nonmonetary remuneration in the form of electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records.

In order to enjoy the protection of the exceptions, parties entering into arrangements for the donation of electronic prescribing or electronic health records technology or services must execute a written agreement that: (i) is signed by the parties; (ii) specifies the items and services being provided, the donor’s cost of the items and services, and the amount of the physician’s contribution (for electronic health records technology and services); and (iii) covers all of the electronic health records items and services to be provided by the donor. This requirement will be met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The

master list should be maintained in a manner that preserves the historical record of agreements.

Most of the exceptions to the physician self-referral prohibition require that the arrangements between the parties be in writing and maintained by one or both of the parties. Given the substantial penalties for even inadvertent violation of the physician self-referral law – that is, repayment of all amounts paid by Medicare for certain designated health services (DHS) provided and billed pursuant to improper referrals between the parties – most parties find that a written agreement is the best and easiest way of proving compliance with the requirements of the exception(s).

The Department plans to initiate the documentation requirements upon the effective date of the final exceptions, which is 60 days following publication in the Federal Register of the final rule.

Here is a proposed outline for the approval of the emergency information collection request.

August 1, 2006	Submit emergency justification to OMB
August 2, 2006	Requested date of OMB approval of emergency justification
August 4, 2006	Date of Display for Emergency FR notice; start of 45-day comment period
August 11, 2006	Target date of publication for emergency FR notice
September 18, 2006	End of 45-day comment period from date of display
September 22, 2006	Requested date of OMB approval