Supporting Statement for Request for Clearance:

Safe Harbor for Federally Qualified Health Centers Arrangements

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SUPPORTING STATEMENT
SAFE HARBOR FOR FEDERALLY QUALIFIED HEALTH CENTERS
ARRANGEMENTS

The Office of Inspector General (OIG) is requesting an approval by OMB on reinstatement without change for data collection 0990-0322 which are requirements associated with a voluntary safe harbor for Federally Qualified Health Centers under the Federal anti-kickback statute. See 72 FR 56632 (October 4, 2007). The safe harbor protects certain arrangements involving goods, items, services, donations, and loans provided by individuals and entities to certain health centers funded under section 330 of the Public Health Service Act.

The anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to five years. Violations of the anti-kickback statute may also result in the imposition of civil money penalties (CMPs) under section 1128A(a)(7) of the Act (42 USC 1320a-7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 USC 1320a-7(b)(7)), and liability under the False Claims Act, (31 USC 3729-33).

Safe harbors are voluntary regulations that describe arrangements that are protected from liability under the anti-kickback statute if all the safe harbor conditions are met. The safe harbor regulations specify various payment and business practices that would not be treated as criminal offenses under the anti-kickback statute, even though they may potentially be capable of inducing referrals of business under the Federal health care programs. Compliance with a safe harbor under the anti-kickback statute is voluntary, and no party is ever required to comply with a safe harbor. Instead, safe harbors offer an optional framework for structuring business arrangements to ensure compliance with the anti-kickback statute. All parties remain free to enter into arrangements that do not qualify for a safe harbor, so long as the arrangements do not involve unlawful payments for referrals under the anti-kickback statute.

We believe that the documentation requirements necessary to enjoy safe harbor protection are not an added paperwork burden, because safe harbor compliance is voluntary; the requirements are consistent with usual and customary business practices; and the time, effort, and financial resources necessary to comply with the requirements would largely be incurred in the normal course of business activities. Section 431 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) **(Attachment A**), which established the health center safe harbor, applies only to the health centers' receipt of goods, items, services, donations, or loans pursuant to a

contract, lease, grant, loan, or other agreement. We believe it is usual and customary for health centers to memorialize contracts, leases, grants, loans, and other similar agreements in writing. Ensuring that such writings are comprehensive and that the actual business activities are accurately reflected by documentation are standard prudent business practices. The only documentation requirement of the safe harbor that potentially imposes an additional recordkeeping burden is the requirement that health centers document the statutorily mandated expected benefit to a medically underserved population.[1] Since serving a medically underserved population is central to the underlying mission of the health centers and the section 330 grant program (and all health centers serve at least one such population), documentation of such benefit would seem to be a prudent business practice to ensure continued compliance, not only with the safe harbor, but also with the section 330 grant program. Moreover, in many cases a health center's section 330 grant documents, in combination with the agreement required under § 1001.952(w)(1), may serve as the documentation of a sufficient benefit to a medically underserved population, to the extent they transparently document that a volume of items or services specified by the section 330 grant requirements will be provided under the agreement.

A. Justification

1. Circumstances Making the Collection of Information Necessary

We developed this safe harbor regulation in accordance with Congress's direction at section 431 of MMA. Section 431 of MMA amended the anti-kickback statute to create a new safe harbor for certain agreements involving health centers. The final rule implementing the safe harbor is found at 72 FR 56632 (**Attachment B**).

In addition to certain enumerated criteria, the statute authorizes the OIG to include "standards and criteria that are consistent with the intent of Congress in enacting" the health center safe harbor. Accordingly, we interpreted the statute to permit us to consider other relevant factors and to establish additional safe harbor standards consistent with the anti-kickback statute and the health center safe harbor. Among the factors we considered is whether arrangements would pose a risk of fraud or abuse to any Federal health care programs or their beneficiaries. To permit effective oversight of protected arrangements

[1] Health centers are also required to provide effective notification to patients reminding patients of their freedom to choose any willing provider or supplier and to provide information about safe harbored arrangements to patients who inquire; however, these disclosures need not be in writing. Instead, we require that health centers provide patient disclosures in a manner reasonably calculated to provide effective notice and to be understood by the patient. We believe the notification requirement will achieve the goal of protecting patients without imposing an added paperwork burden because the notice need not be written.

and determine whether they comply with the fraud and abuse laws, the safe harbor contains documentation requirements.

For an arrangement to fall within the safe harbor, these documentation requirements must be met:

(1) it must be set out in writing (1001.952(w)(1)(i)(A));
(2) the written agreement must be signed by the parties (1001.952(w)(1)(i)(B));
(3) the written agreement must cover, and specify the amount of, all goods, items, services, donations, or loans provided by the individual or entity to the health center (1001.952(w)(1)(i)(C));[2]
(4) the health center must document its basis for its reasonable expectation that the arrangement will benefit a medically underserved population (1001.952(w)(3)); and
(5) the health center, at reasonable intervals, must re-evaluate the arrangement to ensure that it is expected to continue to benefit a medically underserved population, and must document the re-evaluation contemporaneously (1001.952(w)(4)).

Written agreements are fundamental to discouraging fraud and abuse because they promote transparency and accountability. Since July 29, 1991, OIG has published in the *Federal Register* a series of final regulations establishing safe harbors in various areas. A writing requirement has been a common feature of most OIG safe harbor regulations since the first safe harbors were published.

Further, documentation of the expectation of benefit to a medically underserved population implements the statutory requirement at section 431(a)(3) of MMA that all protected arrangements be "pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity." The written agreement requirement ensures that the statutory requirement of a "contract, lease, grant, loan, or other agreement" is met.

2. Information Users

[2] The written agreement will be deemed to cover all goods, items, services, donations, or loans provided by the individual or entity to the health center if all separate agreements between the individual or entity and the health center incorporate each other by reference or if they cross-reference a master list of agreements that is maintained centrally, is kept up to date, and is available for review by the Secretary upon request. Our goal was to provide parties with considerable flexibility and minimize any need to revise existing documentation practices.

OIG does not routinely, affirmatively collect information from parties who choose to participate in the voluntary safe harbor; however, the regulation requires that a master list of agreements between the parties to a safe-harbored arrangement must be made available to the Secretary upon request. The Secretary or the OIG could request and use the master list or underlying written agreements in the event of law enforcement or oversight activities to determine whether arrangements were in compliance with the terms of the safe-harbor and the fraud and abuse laws. The Secretary or the OIG could also request and use the benefit determination that is required under the safe harbor for similar purposes.

Participants in safe-harbored arrangements may also use the information documented pursuant to this safe harbor, for instance, to demonstrate to other parties compliance with the terms of the safe harbor, or to assert an affirmative defense in an enforcement proceeding.

3. Use of Improved Information Technology and Burden Reduction

The documentation requirements of the safe harbor are limited to maintenance of business records and documentation of the basis for the health center's reasonable expectation that the arrangement will benefit a medically underserved population; the OIG will not routinely collect information from parties to safe harbored arrangements, nor are such parties required to routinely report such information to the OIG. Since these documentation requirements are consistent with usual and customary business practices and because the time, effort, and financial resources necessary to comply with the requirements would largely be incurred in the normal course of business activities, there is little opportunity to further reduce this small burden using technology. Parties are free to use technology to maintain their written agreements and their benefit determinations, and, depending on the circumstances, could provide them in electronic format provided their authenticity could be verified.

4. Efforts to Identify Duplication and Use of Similar Information

We are aware of no duplicate collections. We consulted with the Health Resources and Services Administration ("HRSA") and determined that they do not have duplicate requirements; for example, the specific benefit determination requirement in the safe harbor is unique to the safe harbor under section 431 of MMA. And while the specific contracts may be relevant to health center grants, they are not collected in any systematic way. Finally, we note that parties electing to participate in the safe harbor will be documenting unique information about the specific terms of the arrangements they create.

5. Impact on Small Businesses or Other Small Entities

Some of the health centers that choose to avail themselves of the safe harbor may be small entities. However, as discussed above, we believe that the documentation requirements necessary to enjoy safe harbor protection will not be burdensome to health centers because the requirements are consistent with usual and customary business practices and because the time, effort, and financial resources necessary to comply with the requirements would largely be incurred in the normal course of business activities. The safe harbor's documentation requirements have been held to the absolute minimum required for the intended use of the data in protecting fraud and abuse. Moreover, the safe harbor should benefit health centers (and their patients) by increasing their flexibility to engage in transactions involving goods, items, services, donations, and loans that result in conservation of Federal grant dollars and other funding without any risk under the anti-kickback statute.

6. Consequences of Collecting the Information Less Frequently

The safe harbor is voluntary and does not entail a routine, affirmative collection of data from the regulated community. However, health centers that choose to use the safe harbor must, at reasonable intervals, but at least annually, re-evaluate the arrangement to ensure that the arrangement continues to meet the statutory requirement that it is expected to continue to benefit a medically underserved population, and must document the re-evaluation contemporaneously. A yearly interval for documenting this information is related to the usual and customary terms of business arrangements, which are typically denominated in years. Regular, annual documentation is essential to reducing the risk of fraud and abuse. Moreover, if this information were documented less frequently, it could compromise OIG's ability to fulfill its oversight and law enforcement mission. Since safe harbors provide prospective immunity from liability under the Federal anti-kickback statute, it is essential that arrangements that no longer meet the statutory requirements be readily identifiable by the parties and the government, and that the OIG be able to assess an arrangement's fraud and abuse risks using current information. Finally, maintaining up-to-date contract documentation promotes self-policing by the parties to safe-harbored arrangements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Trade Secrets. The safe harbor has no requirement for parties to submit to OIG proprietary, trade secret, or other confidential information. However, to the extent that parties maintain any such information pursuant to this safe harbor and provide it to the OIG, it will be protected to the extent permitted by law. OIG has longstanding practices and procedures for handling such information in the course of its law enforcement and oversight activities.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-day FRN published in the Federal Register on October 1, 2014, pg. 59269-59270, vol.79. There were no comments received.

In connection with the original promulgation of the rule, OIG consulted with the National Association of Community Health Centers, the leading trade organization for health centers.

9. Explanation of Any Payment or Gift

No payment or gift has been or will be provided by the OIG to parties availing themselves of the safe harbor.

10. Assurance of Confidentiality

We make no assurances of confidentiality of information this will be kept private to the extent allowed by law. We note that the safe harbor's documentation requirements do not encompass personally identifying information.

11. Justification for Sensitive Questions

The safe harbor does not entail sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12.A – Annualized Burden Hours

We estimate that the total burden hours for this collection will be 4,983 burden hours per year (1 hour per respondent health center each year).

Type of Respondent	No. of Respondents	No. Responses per Respondent	Avg. Burden hour per Response	Total Burden Hours
Health Center (administrative professional)	4,983	1	1	4,983

Respondents to this safe harbor are health centers (the actual documentation duties are likely performed by administrative professionals employed by the health centers). In 2014, here are approximately 9,967 health center delivery sites in the United States. U.S. Department of Health and Human Services, Health Resources Administration, HRSA Data Warehouse, Health Care Delivery Sites, http://datawarehouse.hrsa.gov/Topics/HccSites.aspx, last visited September 23, 2014. . We estimated that half of the health centers would choose to participate in one safe-harbored arrangement each year. Participating health centers would only need to make one response per year: the initial documentation of an arrangement in year one, and an annual re-evaluation of the arrangement each additional year the arrangement continues to be in place. We estimated the average time burden imposed by the safe harbor per response would be one hour. This estimate was based on the fact that the safe harbor's documentation requirements are largely the same as health centers' customary and usual business practices, with the possible exception of the documentation of a benefit to a medically underserved population, which – for health centers that do not already maintain this documentation for other purposes – could require the creation of a new document that explains the benefit. Thus, the time, effort, and financial resources necessary to comply with the requirements would largely be incurred in the normal course of business activities, and the additional time attributable to the safe harbor would be one hour of burden.

Because the health centers are not required to report information collected in order to have the benefit of the safe harbor, unless requested to do so by the Secretary, we are unable to confirm the accuracy of these estimates.

12.B – Annualized Costs

We estimated that the total annualized cost for this collection will be $99,660 ($20 per respondent health center). We estimated that the additional effort necessary to meet the documentation requirements will take one hour of an administrative professional's time

each year.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Administrative professional	4,983	$20	$99,660

Because the health centers are not required to report information collected in order to have the benefit of the safe harbor, unless requested to do so by the Secretary, we are unable to confirm the accuracy of these estimates.

13. Capital Costs

There are no new annual capital or maintenance costs to health centers that choose to participate in the safe harbor. As discussed above, the documentation requirements align with the usual and customary business practices of health centers.

14. Annualized Cost to the Government

We have spent approximately eight hours of employee time promulgating this rulemaking at a cost of $142 hour; therefore, the anticipated annualized cost to the Federal government is $1,136.00.

15. Program or Burden Changes

This is a reinstatement without change. There is no change to the data collection.

16. Publication and Tabulation

There will be no publication or tabulation of documentation under the safe harbor.

17. OMB Expiration Date

Expiration date display exemption is not requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable.

B. Collection of Information Employing Statistical Methods

As discussed above, the safe harbor does not entail a routine, affirmative collection of data from the regulated community. Use of statistical methods in the collection of

information would not be appropriate to case-by-case oversight and enforcement under the anti-kickback statute, nor would collection of information employing statistical methods improve the accuracy of results.

ATTACHMENTS

A. Section 431 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, section 431

B. Safe Harbor for Federally Qualified Health Centers (72 FR 56632).

C. Notice of proposed rulemaking for a safe harbor for Federally Qualified Health Centers (70 FR 38081).

D. 30-day public comment request (72 FR 63899).

E. 60-day public comment request (76 FR 14398).