DEPARTMENT OF HEALTH AND HUMAN SERVICES

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TO: Mary K. Wakefield, Ph.D., R.N.
Administrator
Health Resources and Services Administration

/S/

FROM: Stuart Wright
Deputy Inspector General
for Evaluation and Inspections

SUBJECT: Memorandum Report: *Quality Assurance and Care Provided at HRSA-Funded Health Centers*, OEI-09-06-00420

This memorandum report provides information about the extent to which health centers maintained quality assurance programs and health center patients received primary health services in four areas: preventive health exams, vaccinations, referrals for specialized treatment, and dental services. It also examines the Health Resources and Services Administration's (HRSA) oversight of the required primary health services in health centers.

SUMMARY

The Public Health Service Act authorizes HRSA to award grants to organizations that provide care in medically underserved urban or rural areas or to medically underserved populations. Reflecting an increased Federal investment, the number of health center patients grew from 10.3 million in fiscal year (FY) 2001 to 17.1 million in FY 2008. Although health center requirements specify which services health centers must make available to patients, they do not establish specific quality standards for these services. We collected information about the quality assurance programs for a sample of 147 health center grantees. To examine the required primary health services, we contracted with medical reviewers to assess medical records for a sample of 448 health center patients (from the same 147 health center grantees) who had at least 2 patient encounters between January 1, 2006, and December 31, 2007, including at least one encounter in the last 6 months of 2007. Finally, we held several meetings and calls with HRSA staff, including staff from the Bureau of Primary Health Care and the Office of Performance Review, to assess HRSA oversight activities. We found that almost all health centers had quality assurance programs. However, insufficient documentation prevented detailed assessments of some medical records. Health services, generally,

were appropriate for most health center patients. During the period of our review, HRSA's oversight and review activities provided limited information about the extent to which individual health center patients received required primary health services. HRSA agreed with each of our four recommendations. We recommend that HRSA (1) specify what elements should be included in quality assurance programs and, in particular, provide more guidance about how grantees conduct their periodic assessments of services; (2) provide more specific guidance concerning what information is required in patient records at health centers; (3) provide more specificity about patients' receipt of required primary health services; and (4) establish procedures to independently assess patients' receipt of primary health services and the adequacy of patients' records.

BACKGROUND

The importance of ensuring the quality of care in health centers funded by HRSA is growing with the increases in Federal investment in health centers and numbers of patients served. In 1975, Congress authorized funding for neighborhood health centers to provide medically underserved communities health and social services. The Health Centers Consolidation Act of 1996[1] amended the Public Health Service Act (the PHS Act)[2] to merge separate authorities for community, migrant, homeless, and public housing health centers into the Consolidated Health Centers program. The PHS Act authorizes HRSA to award grants to organizations that provide care in medically underserved urban or rural areas or to medically underserved populations.[3] FY 2002 marked the start of a multiyear effort to expand the health center program with a goal of doubling the patient population within 5 years. Reflecting the increased Federal investment, the number of health center patients grew from 10.3 million in FY 2001 to 17.1 million in FY 2008.[4]

The Federal investment in health centers continues to increase. Health centers received $2 billion through the American Recovery and Reinvestment Act of 2009 to expand health center capacity and support capital improvements, including the implementation of

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[1] P.L. 104-299.

[2] Section 330 (codified at 42 U.S.C. § 254b).

[3] Pursuant to 42 U.S.C. § 254b, a medically underserved population includes the population of an urban or rural area that has been designated by the Secretary of Health and Human Services (HHS) as an area with a shortage of personal health services. It also may include a population group designated as having a shortage of these services, such as migratory and seasonal agricultural workers, homeless individuals, and residents of public housing.

[4] HHS, *Fiscal Year 2011, Health Resources and Services Administration—Justification of Estimates for the Appropriations Committee*. Accessed at http://hrsa.gov/about/pdf/budgetjust2011.pdf on August 4, 2010.

electronic health records.[5, 6] In FY 2010, the Patient Protection and Affordable Care Act of 2010 (ACA) provided a total of $11 billion in new funding for community health centers over the 5-year period beginning in FY 2011. Of this, $9.5 billion is for patient services and centers' operations. The remaining $1.5 billion is for health center construction and renovation.[7]

Health Center Quality Assurance and Review Requirements

Health centers receiving grants from HHS must comply with monitoring and reporting requirements established by the awarding HHS agency.[8, 9] Health centers are required to provide patients with access to certain required primary health services and to maintain a quality assurance program. Through required quality assurance programs, the grantee assumes the primary responsibility for ensuring quality of care.

Primary Health Service Requirements. Health center service requirements address the availability and provision of care in health centers. Health center requirements fall under four broad areas: need, services, management and finance, and governance.[10] Requirements related to services outline the services that health centers must offer to patients and to access issues, such as the availability of staff and health center hours. Health centers must provide certain required primary health services either directly or through contracts or cooperative arrangements with other health care providers.[11] Although health center requirements specify broad categories of primary health services that health centers must offer to patients, they do not establish specific standards for these services, nor

[5] P.L. 111-5, Division A Title VIII (Feb. 17, 2009).

[6] HHS, *American Recovery and Reinvestment Act—Strengthening Community Healthcare Services*. Accessed at http://www.hhs.gov/recovery/reports/plans/healthcentersservices.pdf on September 11, 2009.

[7] P.L. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152); see, e.g., §§ 5601, 10503.

[8] 45 CFR § 74.51 and 42 U.S.C. 254b(k)(3)(I)(ii).

[9] Furthermore, pursuant to 42 U.S.C. 254b(k)(3)(I)(ii), health centers must develop procedures for compiling and reporting statistics relating to the costs of operations; the patterns of use of their services; the availability, accessibility, and acceptability of their services; and such other matters that the Secretary of HHS may require.

[10] These requirements are intended to ensure that (1) health centers' target population or area is otherwise medically underserved (need); (2) required health services are available, provided by the appropriate staff, and provided within the context of a quality assurance program (services); (3) appropriate management, billing, budget, and data systems are in place (management and finance); and (4) the composition of the board and the conflict-of-interest policies are appropriate (governance). These requirements are found in 42 U.S.C. § 254b, 42 CFR pt. 51c, 42 CFR §§ 56.201–56.604, and 45 CFR pt. 74. A more detailed summary of health center requirements was accessed at http://bphc.hrsa.gov/about/requirements/index.html on July 1, 2011.

[11] 42 U.S.C. § 254b(a)(1).

do they list each individual service that patients might need. However, health centers are required to assess the credentials of their health care practitioners to ensure the adequacy of their training and skills.[12] Some of the primary health services that health centers must offer[13] include:

- basic health services, consisting of
  - health services related to family medicine, internal medicine, pediatrics, and obstetrics;
  - diagnostic laboratory and radiologic services; and
  - preventive services such as prenatal and perinatal services, well-child services, immunizations against vaccine-preventable diseases, and preventive dental services.
- referrals to providers of medical services, including
  - specialty referral when medically indicated and

    other health-related services (including substance abuse and mental health services).[14]

Quality Assurance Program. Health center grantees are required to maintain a quality assurance program, which provides an organizational structure that supports the provision of high-quality patient care.[15] Quality assurance programs must provide for periodic assessments of utilization and quality of health services. These assessments must (1) be conducted by physicians or other licensed professionals under the supervision of physicians, (2) be based on the systematic collection and evaluation of patient records,[16] and (3) identify and document needed changes and the results of such changes.[17]

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[12] HRSA policy requires all health centers to assess the credentials of each licensed or certified health care practitioner. This assessment must "meet the requirement of 42 U.S.C.§233(h)(2) that calls for review and verification of 'the professional credentials, references, claims history, fitness, professional review organization findings, and license status of its physicians and other licensed or certified health care practitioners.' " *Credentialing & Privileging of Health Center Practitioners*, Policy Information Notice 2001-6. Accessed at http://bphc.hrsa.gov/policiesregulations/policies/pin200116.html on August 29, 2011.
[13] 42 U.S.C. § 254b(a)(1). Health centers must provide these services either through the staff and supporting resources of the center or through contracts or cooperative arrangements.
[14] 42 U.S.C. § 254b (b)(1)(A).
[15] 42 CFR § 51c.303(c), 42 CFR 56.303(c), and 42 U.S.C. 254b(k)(3)C).
[16] Pursuant to 42 U.S.C. 254b(n), health centers are required to establish and maintain such records as the Secretary of HHS shall require.
[17] 42 CFR § 51c.303(c), 42 CFR 56.303(c), and 42 U.S.C. 254b(k)(3)C).

HRSA Oversight

Grantees are required to have in place a process for compiling and reporting to HRSA information relating to costs, service utilization, and the "availability, accessibility, and acceptability of [their] services."[18] HRSA monitors and assesses grantees' performance through Uniform Data System (UDS) reporting, grant reviews, and performance reviews.

UDS Reporting. HRSA requires that health center grantees annually submit a core set of data to HRSA's UDS.[19] The UDS includes information at the level of each health center about patient encounters, staffing, and revenue and expenses; HRSA can use this information to monitor and assess grantee performance and to report on overall trends.[20, 21] In 2007 (the period covered by this review), health centers were required to report two measures of grant performance (number of patients served and financial stability) and at least one measure of clinical performance. Each grantee selected its clinical measure from a standardized set of 14 clinical measures (e.g., percentage of pregnant women beginning prenatal care by end of first trimester). Each of these clinical measures—listed in Appendix A—pertains to a particular subgroup (e.g., pregnant women, patients with diabetes) within the general patient population typically served by health centers. Grantees' performance on the one selected clinical measure was examined by HRSA during onsite performance reviews (discussed in the section below on grant and performance reviews).

HRSA has modified requirements related to reporting UDS performance measures since 2007, the period of our review. For 2011 UDS reporting, all health center grantees are required to report data on 11 standardized clinical measures, 2 additional clinical measures related to behavioral and oral health, and 5 standardized financial measures, as listed in Appendix B.[22]

Grant and Performance Reviews. HRSA annually assesses health center grantees' compliance with health center requirements.[23, 24] HRSA reviews grantees' Health Care and Business Plans (plans) to evaluate their expected and actual grant performance. In their

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[18] 42 U.S.C. § 254b(k)(3)(I)(ii).
[19] Ibid.
[20] *Health Center Data*. Accessed at http://www.bphc.hrsa.gov/uds/ on May 6, 2010.
[21] Introduction to the *2007 Uniform Data System Reporting Manual*. Accessed at http://bphc.hrsa.gov/healthcenterdatastatistics/reporting/2007udsreportingmanual.pdf on February 15, 2012.
[22] *Clinical and Financial Performance Measures.* Updated June 20, 2011. Accessed at http://bphc.hrsa.gov/policiesregulations/performancemeasures/updatedfy2012measures.pdf on August 30, 2011.
[23] Pursuant to 42 CFR §§ 51c.305 and 56.305.
[24] Pursuant to 42 CFR §§ 51c.303 and 56.303.

plans, grantees outline their clinical and management goals (e.g., health outcomes, services offered, and recruitment activities) and the objectives; key action steps; expected outcomes; data, evaluation and measurement; and points of contact related to these goals. HRSA reviews these plans to evaluate the extent to which prospective grantees will be able to meet program requirements and current grantees have achieved established goals. Starting in 2009, the required UDS performance measures were included in all grantee plans, along with other goals specific to individual grantees.

During the period of our review, HRSA—in addition to conducting grant reviews—also conducted onsite performance reviews of health center grantees at least once during the grantees' 3–5 year project period.[25, 26] During these performance reviews, HRSA examined grantees' progress on their performance measures including the number of patients served, financial stability measures, and the selected clinical measure.[27] The review team and the grantee discussed, in particular, external and internal factors that influenced the grantee's performance on clinical and other performance measures. HRSA and the grantee also discussed options for improvement.[28] The *Performance Review Protocol*, used during onsite visits, included suggested questions concerning grantees' quality assurance/improvement plans, but it did not specify how or whether review teams were to collect or review information about these plans.[29] HRSA stopped conducting performance reviews after November 2009. After that time, onsite HRSA reviews primarily assessed grantees' ability to comply with health center program requirements, among other issues.[30] According to HRSA staff, site visits also are used to review clinical and financial issues raised during quarterly calls between health center grantees and HRSA project officers.

METHODOLOGY

Sample Selection

Health Center Selection. Using HRSA data, we selected a stratified random sample of 150 health center grantees that (1) were funded in 2005, (2) were still operating in 2006, and (3) had received a performance review between 2004 and 2006.[31, 32] One stratum

[25] HRSA, *Performance Review Protocol*, revised December 2004. This document is no longer available online.
[26] The *Performance Review Protocol* did not establish required timeframes for reviews.
[27] HRSA, *Performance Review Protocol*, revised December 2004.
[28] Ibid.
[29] Ibid.
[30] Requirements established pursuant to 42 CFR §§ 51c.303 and 56.303. Other issues are pursuant to 42 CFR §§ 51c.305 and 56.305.
[31] HRSA reported 1,002 health center grantees in 2006. *2006 National Aggregate UDS Data: Table 2.* Accessed at http://bphc.hrsa.gov/uds/2006data/national/nationaltable2.htm on December 7, 2010.

consisted of the population of the 75 largest health centers, based on number of patients; we included all of the 75 largest health centers in our sample. The other stratum consisted of the remaining population of 315 health centers, from which we randomly selected 75 health centers.[33] After excluding three of the sampled health center grantees because of ongoing Office of Inspector General (OIG) investigations, we sent letters and information requests to the remaining 147 health center grantees.

Patient Selection. We requested information about patient encounters from the 147 sampled health center grantees to help us select a sample of patients for medical review. We sent letters to each of the sampled health center grantees to request that they provide information about patient encounters in 2006 and 2007. The letters requested that the health center grantees provide the name, identification number, and date of birth for all patients with at least one encounter, at any of their health center sites, in the last 6 months of 2007.[34] For each of these patients, we also requested the number of encounters at the health center in 2006 and, separately, in 2007. We received patient lists from 142 of the health center grantees. We used this information to select a sample of patients who had at least two patient encounters between January 1, 2006, and December 31, 2007, including at least one encounter in the last 6 months of 2007. From the patient lists of the 142 health centers, we selected a sample of 490 patients. We collected medical records for the sampled patients in September 2008, so services provided through that time could have been included in our medical review.

Medical Review of Health Center Records

We worked with a medical review contractor that contracted with three physicians and three dentists, all with current and/or prior health center experience, to review the status of primary health services among patients in four categories. Using available information about patients' health status and medical history, they determined whether each patient

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[32] Approximately 41 percent of health centers operating in 2006 met these criteria.

[33] The number of patients was based on 2005 UDS data.

[34] When requesting information about patients from health center grantees, we instructed them to use the definition of patient encounters included the *2007 Uniform Data System Reporting Manual*. HRSA's 2007 UDS Reporting Instructions for Section 330 Grantees defines encounters as "face-to-face contacts between a patient and a provider who exercises independent professional judgment in the provision of services to the patient. To be included as an encounter, services rendered must be documented in the patient's record." Encounters do not include large-scale efforts such as group immunizations, screening programs, or communitywide programs such as health fairs. Furthermore, the provision of laboratory tests, x-rays, immunizations, tuberculosis tests, and prescription refills are not counted as encounters if not accompanied by an additional service.

received necessary services.[35] We developed a medical review instrument,[36] using feedback from the medical reviewers, to assess:

- preventive health exams[37] (e.g., hearing[38] and vision exams, weight and blood pressure checks, and cholesterol screenings),
- vaccinations (e.g., polio; influenza; pneumococcal; measles, mumps, rubella; varicella (chicken pox); and diphtheria, tetanus, pertussis),
- referrals for specialized treatment (e.g., allergy, behavioral health, dermatology, HIV testing and/or treatment, health education, nephrology, nutritionist services, ophthalmology/optometry, and orthopedics), and
- dental services (e.g., dental exams, cleanings, fillings, and x-rays).

Medical reviewers made overall assessments based on both the number and potential consequence of individual exams or services within each type of service they determined to be adequate. For example, a medical reviewer could have determined that omission of vision and blood pressure exams reflected inadequate overall preventive health services for a patient with diabetes, but not for a patient without diabetes. Reviewers generally determined that services were inadequate if, based on their judgment:

- services needed by the patient were not offered,
- services needed by the patient were not provided in a timely manner, or
- unnecessary services were provided to the patient.

Analysis. We conducted all analyses separately for patients in different age groups. For vaccinations, we conducted separate analyses for each of the following age groups: patients

[35] In some cases, preventive health guidelines recommend against certain patients receiving specific services, such as a vaccination, given their health status or medical history. In these cases, medical reviewers would have determined that the status of this service was appropriate.

[36] We developed the medical review instrument based on preventive health guidelines issued by organizations such as the U.S. Preventive Services Task Force, the American Academy of Pediatrics, and the American Diabetes Association, among other national and professional associations.

[37] The term "preventive health exams" is not listed as a required primary health service pursuant to 42 U.S.C. 254b(b)(1)(A)(i)(I) and 42 CFR § 51c.102(h), or as a supplemental health service pursuant to 42 CFR § 51c.102(j). We use this term broadly to encompass a variety of preventive health services, including screenings, examinations, and laboratory tests.

[38] Some of the health services assessed by our medical reviewers, such as hearing exams for adult patients, are not explicitly listed as required primary health services pursuant to 42 U.S.C. 254b(b)(1)(A)(i)(I) and 42 CFR § 51c.102(h) or supplemental health services pursuant to 42 CFR § 51c.102(j). However, we included these services in our review because they have been recommended in guidance issued by national and/or professional health care associations for the general population and/or for individuals in certain age groups or with particular health conditions.

aged 0–18, 19–49, and 50 and older.[39] For each of the other service types, we conducted separate analyses for pediatric patients (0–18) and adult patients (19 and older). The results of the medical review are projected to a subset of all health center patients.[40] Appendix C lists the confidence intervals for all medical review statistics presented in this report.

Limitations

Assessments of health center services in this report are based on the professional judgment of medical reviewers. By their nature, medical reviews involve some subjectivity. Differences in training and certification could result in differences in judgment. We conducted two pretests and made modifications to the review instrument to better standardize the medical review process.

Generally, the medical review results are based on documentation of services received or needed during encounters at health centers. In some cases, health center patients may have received services from other health providers. Unless documented in health center records, this information was not available to medical reviewers, and, therefore, not incorporated into medical reviewers' assessments of patients' receipt of services.

See Appendix D for a detailed discussion of the methdology.

This inspection was conducted in accordance with the *Quality Standards for Inspections* approved by the Council of the Inspectors General on Integrity and Efficiency.

[39] The Centers for Disease Control and Prevention (CDC) issues separate Recommended Immunization Schedules for patients aged 0–6, 7–18, 19–49, 50–64, and 65 and up. We combined all pediatric patients into a single group and patients aged 50 and older into a single group for analysis because of the relatively small number of such patients in our sample.

[40] The results are projected to patients with at least two patient encounters between January 1, 2006, and December 31, 2007 (including at least one in the last 6 months of 2007), at health centers that (1) were funded in 2005, (2) still operating in 2006, and (3) had received a performance review between 2004 and 2006.

RESULTS

Almost All Health Centers Reported Maintaining Required Quality Assurance Programs

Almost all health center grantees reported that they maintain written quality assurance programs. Only 2 percent of grantees indicated that they did not maintain a written quality assurance program.[41] Of the 141 grantees that completed surveys, 134 provided some documentation of their quality assurance program. Most of these grantees maintained a written quality assurance plan created to describe the grantees' quality assurance activities. Others did not maintain a separate quality assurance plan, but instead outlined their quality assurance activities in other health center guidance, such as policy and procedures manuals, clinical guidance, quality review protocols, and risk management guides.

Ninety-Seven Percent of Grantees Reported Conducting Required Periodic Assessments as Part of Their Quality Assurance Program. Most health center grantees reported that they conduct periodic assessments of health center services as part of their quality assurance program. Among the health center grantees that indicated they have a written quality assurance program, 97 percent indicated that they have conducted a periodic assessment (hereafter assessment) of the services provided by their health centers.[42]

The majority of health center grantees indicated that they conduct assessments at least once a year. Among the health center grantees that reported conducting assessments, 46 percent indicated that they conduct assessments once a year and 9 percent indicated that they conduct assessments every 6 months. Other grantees noted that they conduct assessments monthly or quarterly, whereas some noted that they continuously assess the services provided to patients. Some health center grantees reported conducting multiple assessments staggered throughout the year, with reviews of different types of services or patients assigned to specific months.

[41] One health center responded that it did not maintain a written quality assurance program, whereas a second health center grantee indicated that although it did not maintain a written quality assurance program, it tracked some clinical data and participated in a HRSA disease collaborative. The information provided by the latter grantee did not appear to indicate that the grantee maintained an organized quality assurance program. We asked health center grantees to send documentation of their quality assurance programs with their completed surveys.

[42] If a health center grantee indicated that it did not maintain a written quality assurance program, the grantee was not required to respond to the rest of the questions on the survey, including those involving periodic assessments.

Most health center grantees indicated that they reviewed patient medical records as a part of their assessments. Among the health center grantees that reported conducting assessments, 91 percent indicated that they review patient medical records. Among grantees that reported reviewing medical records as part of their assessments:

- 82 percent select records randomly,
- 47 percent select records from certain types of patients (e.g., pediatric patients),
- 30 percent review records from all health center patients, and
- 22 percent review records of certain provider types (e.g., all dentists, providers being credentialed).[43]

Among health center grantees that conducted assessments, most reported assessing medical records and documentation (83 percent) and quality of care (82 percent), with fewer assessing patient outcomes (61 percent), service trends (57 percent), and the medical necessity of services (35 percent).

Most Quality Assurance Programs Addressed the Primary Health Services Provided by Health Center Grantees. Quality assurance programs addressed primary health services through the implementation of clinical protocols and the measurement of patient outcomes. For example, most health center grantees reported that their quality assurance programs specifically addressed clinical protocols for diabetes screening[44] and/or care (89 percent) and immunizations (87 percent). Grantees also reported addressing patient outcomes in their quality assurance programs, including outcomes related to diabetes screening and/or care (92 percent) and immunizations (81 percent). Table 1 highlights the clinical protocols and patient outcomes often included in health center grantees' quality assurance programs.

[43] These percentages do not sum to 100 percent because some health center grantees reported multiple assessments for which they used different methods for selected patient records.

[44] Although diabetes screening is not explicitly included as a required primary health service pursuant to 42 U.S.C. 254b(b)(1)(A)(i)(I), health centers may have developed protocols for this and other services based on guidance issued by professional and/or national health care associations.

Table 1: Selected Clinical Protocols and Patient Outcomes Addressed in Health Center Grantees' Quality Assurance Programs

Element Type	Element	Percentage of Health Center Grantees That Addressed Element
Clinical Protocols	Diabetes screening/care	88.7%
	Immunizations	86.9%
	Hypertension screening/care	81.4%
	Cervical cancer screening	80.3%
	Breast cancer screening	79.4%
	Colon cancer screening	79.4%
	Cholesterol screening/care	77.2%
	Pediatric care	76.8%
	Dental care	69.0%
	Prenatal care	63.9%
Patient Outcomes	Diabetes screening/care	91.9%
	Immunizations	81.4%
	Hypertension screening/care	72.8%
	Cervical cancer screening	68.4%
	Breast cancer screening	66.4%
	Cholesterol screening/care	66.4%

Source: OIG analysis of survey data, 2011.

Most quality assurance programs also addressed patients' access to the primary health services provided by health centers. Approximately 86 percent of grantees reported addressing the availability of clinical staff. Similarly, 85 percent of grantees reported that their quality assurance program specifically addressed the convenience of health center hours, and approximately 81 percent of health center grantees reported addressing wait times for scheduled appointments. Most grantees also addressed the availability of translation services (82 percent) and the affordability of care (77 percent).

Most grantees also addressed the adequacy of training and review of clinical staff in their quality assurance programs. For example, 86 percent addressed continuing education for medical staff, 86 percent addressed the verification of credentials for health center staff providers, and 85 percent addressed staff education on health center policies.

Although Most Health Centers Reported Addressing Medical Records As Part of Their Quality Assurance Programs, Medical Reviewers Were Not Able To Determine the Adequacy of At Least One Type of Service For 45 Percent of Patients Because of Insufficient Documentation

Most grantees addressed medical records and documentation as a part of their quality assurance plans. Overall, approximately 89 percent of grantees with quality assurance programs reported that they addressed the accuracy and completeness of patient medical records in their quality assurance programs. Among all health center grantees that conducted assessments as part of their quality assurance programs, 83 percent reported that they assessed health center documentation and medical records.

Although most health centers addressed medical records in their quality assurance programs, records for approximately 45 percent of health center patients contained insufficient documentation for reviewers to assess at least one type of service included in our review.[45] For each type of service, reviewers either assessed the adequacy of services or indicated that they could not do so, primarily because of insufficient documentation on the services received by patients or patients' health status. As illustrated in Table 2, vaccinations often lacked sufficient documentation for reviewers to determine the adequacy of services.[46] Approximately 44 percent of health center patients' records lacked sufficient documentation for reviewers to determine the overall adequacy of vaccinations. Although documentation of vaccinations was sufficient for most pediatric patients, it was frequently missing for adults.

[45] Among the 134 grantees that provided documentation of their quality assurance programs, 95 provided a document that was dated from 2007 or earlier, whereas 24 provided a document dated from 2008. The documentation provided by the remaining grantees was undated or contained multiple dates. As a result, the documentation available in some patients' medical records could have predated specific documentation-related guidance included in the quality assurance programs that we reviewed.

[46] If reviewers lacked sufficient information, they did not make determinations about the adequacy of care.

Table 2: Availability of Documentation in Patients' Records

Type of Service	Patient Age	Percentage of Patients With Insufficient Documentation for Type of Service
Preventive health exams	All patients (n=399)	5.3%
Vaccinations	All patients (n=405)	44.0%
	0–18 (n=125)	*17.3%*
	19–49 (n=163)	*62.5%*
	50 and older (n=117)	*46.6%*
Referrals for specialized treatment	All patients (n=407)	2.5%
Dental services	All dental patients (n=91)	19.0%*

Source: OIG analysis of medical review data, 2011.

* Among patients who received at least one dental service.

Primary Health Services, Generally, Were Appropriate For Most Health Center Patients

Medical reviewers assessed four types of primary health services among health center patients: preventive health exams, vaccinations, referrals for specialized treatment, and dental services. Health center requirements specify broad categories of primary health services that health centers must provide to patients. However, the requirements do not establish specific standards for these services, nor do they list each individual service that might be needed by patients. Therefore, we relied on the professional judgment of medical reviewers to assess each type of service. For each type of service, medical reviewers first assessed individual exams and services, such as vision exams, polio vaccinations, referrals for allergy treatment, and dental fillings.[47, 48] After assessing the

[47] When assessing each of the individual preventive health exams, vaccinations, referrals, and dental services on the medical review instrument, reviewers determined whether care was "appropriate," "inappropriate" or, because of the patients' age or gender, "not applicable." Inappropriate services were those that, in reviewers' judgment, were inadequate based on the patients' history and health status. Reviewers also indicated whether they could not determine the adequacy of individual services, generally because documentation in the patients' record was incomplete. If reviewers lacked sufficient information, they did not make determinations about the adequacy of care.

[48] Some of the health services assessed by our medical reviewers are not explicitly listed as required primary health services pursuant to 42 U.S.C. 254b(b)(1)(A)(i)(I) and 42 CFR § 51c.102(h) or supplemental health services pursuant to 42 CFR § 51c.102(j). However, we included these services in our review because they have been recommended in guidance issued by national and/or professional health care associations for the general population or for individuals in certain age groups or with particular health conditions.

individual exams and services, reviewers made an overall assessment of the adequacy of each type of service. Reviewers determined whether services overall in each area were adequate or inadequate, or indicated that they could not determine the adequacy of services. Reviewers' determination that services were adequate did not necessarily indicate that the health center provided these services to the patient, but rather reviewers' judgment that, based on available documentation, the patient had, at the time of the review, received care that was consistent with established guidelines and did not fail to receive a necessary service. Table 3 summarizes medical reviewers' overall determinations of the adequacy of the four types of primary health services received by health center patients.

Table 3: Overall Medical Reviewer Determinations of Four Service Types

Service Type	Percentage Determined Adequate	Percentage Determined Inadequate
Preventive health exams	68.4%	26.4%
Vaccinations	36.8%	19.2%
Referrals	86.1%	11.4%
Dental services	74.2%	6.8%

Source: OIG analysis of medical record review, 2011.

If reviewers determined that either overall or individual services were inadequate, they indicated why. In most but not all such cases, medical reviewers indicated that patients did not receive necessary services. For a small number of cases, medical reviewers determined that services were inadequate because necessary services were not received in a timely manner or because patients received medically unnecessary services. The estimates presented in this finding represent the percentage of patients (among all patients whose records were reviewed) that, according to medical reviewers, did not receive necessary services.

Medical Reviewers Determined That Approximately 25 Percent of Health Center Patients Did Not Receive Necessary Preventive Health Exams. Medical reviewers determined that overall preventive health services were inadequate for approximately one in four patients because patients did not receive needed preventive health exams.[49, 50] Specifically, in the professional judgment of medical reviewers, approximately 29 percent of adult patients and

[49] These cases represent most, but not all, of the preventive services that reviewers determined to be inadequate.
[50] Based on the documentation included in their records.

17 percent of pediatric patients did not receive necessary preventive health exams. Table 4 shows some of the individual preventive health exams not received by health center patients.[51] In particular, reviewers reported that approximately 21 percent of adults did not receive necessary colon cancer screening exams. Similarly, approximately 20 percent of adults did not receive necessary cholesterol screening exams. Among pediatric patients, approximately 16 percent did not receive necessary hearing exams and 15 percent did not receive necessary developmental screenings.

Table 4: Medical Reviewer Assessments of Necessary Preventive Health Exams Not Received

Preventive Health Exam	Patient Age Group	Percentage That Did Not Receive Necessary Exams
Colon screening (i.e., fecal occult blood, sigmoidoscopy, or colonoscopy)	Adult	21.3%
Cholesterol screening	Adult	20.3%
Blood sugar level screening	Adult	9.6%
Vision	Adult	7.5%
Hearing	Pediatric	15.6%
Developmental screening	Pediatric	14.7%
Blood pressure	Pediatric	10.7%
Vision	Pediatric	11.5%

Source: OIG analysis of medical record review, 2011.

Approximately 17 Percent of Patients Did Not Receive Necessary CDC-Recommended Vaccinations. Medical reviewers reported that vaccinations were inadequate for approximately 17 percent of patients because they did not receive necessary vaccinations. Overall, vaccinations for approximately 24 percent of patients aged 50 and older, 17 percent of patients aged 19–49, and 10 percent of patients aged 0–18 were inadequate because the patients did not receive necessary vaccinations. Table 5 displays some of the individual vaccinations missing for patients in the different age groups.[52]

[51] Reviewers assessed the adequacy of 13 individual preventive health exams. The individual exams assessed for adult and pediatric patients varied slightly.
[52] Reviewers assessed the appropriateness of 12 individual vaccinations included on CDC's recommended schedules. The individual vaccinations assessed varied slightly for patients of different ages.

Table 5: Medical Reviewer Assessments of Necessary Vaccinations Not Received

Vaccination	Patient Age	Percentage That Did Not Receive Necessary Vaccinations
Influenza[53]	50 and older	25.0%
Pneumococcal	50 and older	19.1%
Diphtheria, tetanus, pertussis	50 and older	16.1%
Influenza	19–49	14.9%
Diphtheria, tetanus, pertussis	19–49	14.0%
Hepatitis B	19–49	4.4%
Influenza	0–18	30.2%
Varicella (chicken pox)	0–18	12.0%
Hepatitis A	0–18	8.1%

Source: OIG analysis of medical record review, 2011.

Approximately 10 percent of health center patients did not receive necessary referrals. Medical reviewers determined that referrals for specialized treatment were inadequate for approximately 10 percent of patients because they did not receive needed referrals. Medical reviewers did not assess whether patients actually received services from the appropriate specialists, but rather whether a necessary referral to the appropriate specialist was documented in patients' records. Approximately 11 percent of adult patients and 8 percent of pediatric patients did not receive needed referrals.[54] Table 6 displays some of the referrals that were not provided to adult health center patients. For example, almost 8 percent of adult patients did not receive needed referrals for HIV/AIDS testing and/or treatment. Among pediatric patients, referrals for necessary laboratory tests (3 percent) and hearing services (2 percent) were not received for a relatively small percentage of patients.

[53] It is important to note that vaccination rates in the general population are not always consistent with the CDC-recommended schedule. For example, although we cannot make a direct comparison because our review assessed the adequacy of vaccinations (as opposed to actual vaccination rates), in 2007, only 36 percent of adults aged 50–64 and 66 percent of adults aged 65 and older reported receiving an influenza vaccination. *Self-reported influenza vaccination coverage trends 1989–2007*, National Health Interview Survey. Accessed online at http://www.cdc.gov/flu/professionals/vaccination/pdf/NHIS89_07fluvaxtrendtab.pdf on September 8, 2010. Similarly, approximately 17 percent of adults aged 50–64 and 58 percent of adults aged 65 and older reported receiving a pneumococcal vaccination in 2007. *Self-reported pneumococcal vaccination coverage trends 1989–2007*, National Health Interview Survey. Accessed online at http://www.cdc.gov/flu/professionals/vaccination/pdf/NHIS89_07ppvvaxtrendtab.pdf on September 8, 2010.

[54] Reviewers assessed the appropriateness of referrals for 29 types of specialized care.

Table 6: Medical Reviewer Assessments of Necessary Referrals Not Received by Adult Patients

Referral	Percentage That Did Not Receive Necessary Referrals
HIV/AIDS testing and/or treatment	8.0%
Laboratory tests	5.1%
Ophthalmology/optometry services	4.9%
Nutritionist services	4.6%
Health education	4.4%

Source: OIG analysis of medical record review, 2011.

Approximately 2 Percent of Dental Patients Did Not Receive Necessary Dental Services. According to medical reviewers' assessments, only 2 percent of dental patients received inadequate overall dental care because they did not receive necessary services. In our sample of 32 pediatric patients with health center dental records, medical reviewers determined that only one patient (3 percent) did not receive necessary dental services. Similarly, only one adult patient in our sample of 59 adult dental patients (2 percent) did not receive necessary dental services.

HRSA Review Activities Provided Limited Information About the Extent to Which Individual Health Center Patients Received Required Primary Health Services

HRSA oversight in 2007, the period covered by our review, was intended to collect core clinical data, ensure grantee compliance with program requirements, and support grantee efforts to improve their programs; it was not intended to determine the extent to which health center patients received primary health services.

HRSA Reviews Did Not Assess the Required Primary Health Services Received by Health Center Patients. According to HRSA staff, the agency did not independently collect and/or review patient medical records or other health information to assess and/or verify the services received by individual health center patients. HRSA onsite reviews assessed grantees' success at achieving their clinical and management goals, and determined whether technical assistance was necessary. Through its UDS, HRSA received clinical information about a subset of health center services and/or patients, but this information did not

necessarily reflect the range of care received by most health center patients. Even with the most recent update to UDS reporting, performance measures might not provide HRSA with comprehensive information about individual health center patients' care.

The Lack of Detailed Requirements for Quality Assurance Programs May Have Limited Their Usefulness in Ensuring That Patients Receive Necessary Primary Health Services. Requirements and reviews for quality assurance programs were broad and did not always ensure that patients receive necessary services. Approximately 94 percent of grantees[55] reported that HRSA staff reviewed their overall quality assurance program, and 86 percent[56] reported that HRSA staff reviewed their assessments. However, beyond the requirement that grantees must develop and maintain quality assurance programs that provide for assessments of services, the requirements provided few specifics about the issues to be addressed in quality assurance programs. We collected quality assurance plans that ranged from four to several hundred pages. In addition, requirements specified that grantees must conduct assessments of services, but did not specify the frequency of these assessments, the services to be included, or the review methods to be used. Most grantees reported that they assessed medical record documentation and health services as a part of their quality assurance programs and internal assessments. However, medical reviewers often could not determine the adequacy of services because of insufficient documentation and, in other cases, judged that patients did not receive necessary services.

RECOMMENDATIONS

Health centers provide a range of health services to medically underserved communities. Ninety-seven percent of health center grantees maintained required quality assurance programs and conducted internal assessments of their services. Although 89 percent of grantees indicated that their quality assurance programs addressed the accuracy and completeness of medical records, medical reviewers determined that 45 percent of patient records did not contain sufficient information for them to assess at least one type of service. Primary health services, generally, were appropriate for most health center patients. During the period of our review, HRSA's oversight was intended to collect core clinical data, ensure grantee compliance with program requirements, and support grantee efforts to improve their programs; it was not intended to directly assess the receipt of required primary health services by health center patients, and provided limited information about

[55] Among grantees that reported maintaining a quality assurance program.
[56] Among grantees that reported conducting assessments.

the services actually received by health center patients. Therefore, we recommend that HRSA:

Provide More Specific Guidance About What Grantees Should Address in Their Quality Assurance Programs and How They Should Conduct Their Periodic Assessments

Health center grantees must maintain required quality assurance programs and, through these quality assurance programs, periodically assess their services. However, requirements provide little detail about what quality assurance programs and assessments must address. HRSA should specify what elements should be included in quality assurance programs and, in particular, provide more guidance about how grantees conduct their periodic assessments of services. For example, HRSA could require all grantees to review records for a random sample of patients to assess the extent to which patients received required primary services as a part of their assessments. In addition, HRSA could require health centers to assess the adequacy of medical records.

Provide More Specific Guidance Concerning What Information is Required in Patient Records at Health Centers

Incomplete medical records limit health providers' ability to determine what health services their patients need or receive. HRSA should provide explicit guidance concerning the documentation that must be maintained in all health center records. HRSA could develop guidance based on standards issued by national or professional associations or require health center grantees to follow established standards and offer technical assistance, as appropriate.

HRSA also should continue to support health center grantees' efforts to implement electronic record systems. Medical reviewers noted that electronic health records were more organized and legible than handwritten paper records. HRSA's support of health center grantees' transition to electronic health records, through the American Recovery and Reinvestment Act and other agency funding, may improve health centers' ability to maintain complete medical record documentation.

Provide More Specificity About the Required Primary Health Services

Although health center requirements indicate the broad primary health services that grantees must provide, they do not include specific quality standards for these services. HRSA should provide more guidance about the services that should be received by health center patients. To ensure that patients receive necessary services, HRSA could require explicitly that health center grantees identify specific preventive health guidance or

recommendations that their health care practitioners will follow. HRSA could recommend to grantees specific guidance issued by organizations and agencies such as the U.S. Preventive Services Task Force, CDC, or other national and/or professional health associations.

Establish Procedures To Independently Assess Patients' Receipt of Primary Health Services and the Adequacy of Patients' Records

Although health center grantees maintain the primary responsibility for the care received by their patients, HRSA oversight should provide the agency with more information about the extent to which health center patients receive required primary health services. UDS reporting does not provide information about the services received by most health center patients. HRSA should develop a review process that would allow it to assess the primary health services received by a cross-section of health center patients. This process also should assess the adequacy of medical record documentation. For example, HRSA could collect and review a representative sample of patient records to determine the extent to which patients received adequate care. In addition, HRSA could examine the extent to which expected documentation, such as vaccination records and patient medical histories, is maintained in a sample of patient records. During reviews, HRSA also could determine the extent to which grantees implemented elements in their quality assurance programs, in particular those related to patients' receipt of primary health services and the adequacy of medical record documentation.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its written comments on our draft, HRSA highlighted the achievements of health centers in providing quality primary health care to underserved communities and its own increasing focus on quality improvement. Although our review included health records and services through 2007, HRSA cited key initiatives and activities implemented since that time, including emphasizing evidence-based quality improvement practices and evaluating the quality and impact of health care services. HRSA also cited recent research highlights showing favorable statistics for health center patients in comparison to other populations.

In response to our first recommendation—to provide more specific guidance about what grantees should address in their quality assurance programs—HRSA stated that it is in the process of developing specific policy guidance on quality improvement and quality assurance plans including periodic assessments, in accordance with the statutory requirements.

In response to our second recommendation—to provide more specific guidance about what information is required in patient records at health centers—HRSA stated that it fully supports the adoption of electronic health records that meet the "Meaningful Use" criteria established by HHS's Office of the National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services. OIG supports HRSA's efforts to expand the adoption of electronic health records in health centers; these efforts will help to establish clear expectations for what information should be documented in patient records. We anticipate receiving documentation from HRSA regarding its 2010 modification to the UDS to require all health centers to report their specific electronic health record activities.

In response to our third recommendation—to provide more specificity about the required primary health services—HRSA said that national variation in health centers' scope of practice and the needs of the target populations limit its ability to specify and/or require certain procedures or more detailed aspects of core primary and preventive health services. HRSA stated that it will continue to endorse the most current nationally recognized, evidence-based clinical practice guidelines and protocols, such as those set forth by the U.S. Preventive Services Task Force, to offer as a guide to providers for delivering primary health services. OIG supports HRSA's endorsement of evidence-based practice guidelines and encourages the agency to require health centers to include a reference to nationally recognized clinical practice protocols in the centers' primary health services policies for providers.

Finally, in response to our fourth recommendation—to establish procedures to independently assess patients' receipt of primary health services and the adequacy of patient records—HRSA stated that it is in the process of updating its site-visit protocol to add a focus on such reviews. In particular, future site visits will involve reviews/audits of a sample of patient records.

For the full text of HRSA's comments, see Appendix E.

APPENDIX A

Clinical Measures for 2007 Health Center Grantee Performance Reviews[57]

1. Perinatal (Effort): Percentage of pregnant women beginning prenatal care by end of first trimester.
2. Perinatal (Effort): Percentage of women who had a postpartum visit within 42 days after delivery.
3. Perinatal (Effort): Percentage of newborns who had a followup visit within 14 days of birth.
4. Child (Effort): Percentage of children 5 through 18 years of age diagnosed with "persistent" asthma who were prescribed appropriate medications.
5. Adolescent (Effort): Percentage of adolescents who had both a documented Behavioral Risk Assessment and a related counseling visit.
6. Adult (Outcome): Percentage of adults diagnosed with an abnormal lipid profile whose levels are under control.
7. Adult (Effort): Percentage of adults with abnormal breast, cervical, or colon cancer screening results for which referral and/or treatment has been initiated within 30 days of test completion.
8. Adult (Outcome): Percentage of adults diagnosed with hypertension whose blood pressure is under control.
9. Adult (Effort): Percentage of adults who are tobacco users who have received counseling and/or a treatment plan to quit.
10. Adult (Outcome): Percentage of adults with type 1 or type 2 diabetes whose last glycated hemoglobin (HbA1c) level was less than 7 percent.
11. Oral (Outcome): Percentage of dental patients with a comprehensive oral exam and a treatment plan completed within a 12-month period.
12. Mental (Effort & Outcome): a. Percentage of all adult patients with screening for depression (Effort) or b. Percentage of patients with major depression who have a 50-percent decrease in depression severity score (Outcome).
13. All Life Cycles (Outcome): Percentage of child, adolescent, adult, geriatric, or HIV/AIDS patients with appropriate immunizations.

[57] Health Resources and Services Administration guidance. This information is no longer available online.

14. All Life Cycles (Effort): Percentage of child/adolescent patients or adult patients with a Body Mass Index indicating overweight or obesity who have received healthy weight counseling and/or other related interventions or treatment.

APPENDIX B

2011 Clinical and Financial Performance Measures[58]

Outreach/Quality of Care

1. Percentage of pregnant women beginning prenatal care in the first trimester
2. Percentage of children with 2nd birthday during the measurement year with appropriate immunizations
3. Percentage of women 21–64 years of age who received one or more tests to screen for cervical cancer
4. Percentage of patients age 2 to 17 years who had a visit during the current year and who had Body Mass Index (BMI) Percentile documentation, counseling for nutrition, and counseling for physical activity during the measurement year
5. Percentage of patients age 18 years or older who had their BMI calculated at the last visit or within the last 6 months and, if they were overweight or underweight, had a followup plan documented
6. Percentage of patients age 18 years and older who were queried about tobacco use one or more times within 24 months
7. Percentage of patients age 18 years and older who are users of tobacco and who received (charted) advice to quit smoking or tobacco use
8. Percentage of patients age 5 to 40 years with a diagnosis of persistent asthma (mild, moderate, or severe) who were prescribed either the preferred long-term control medication or an acceptable alternative pharmacological therapy during the current year

Health Outcomes/Disparities

1. Percentage of diabetic patients whose HbA1c levels are less than 7 percent, less than 8 percent, less than or equal to 9 percent, or greater than 9 percent
2. Percentage of adult patients with diagnosed hypertension whose most recent blood pressure was less than 140/90
3. Percentage of births less than 2,500 grams to health center patients

[58] Clinical and financial performance measures accessed online at http://bphc.hrsa.gov/policiesregulations/performancemeasures/index.html on February 22, 2012.

Additional Clinical Measures

In addition to the above Uniform Data System clinical measures, health centers must include

1. One Behavioral Health (e.g., Mental Health or Substance Abuse) and
2. One Oral Health performance measure of their choice in the Health Care Plan

Financial Viability/Costs

1. Total cost per patient
2. Medical cost per encounter
3. Change in net assets to expenses ratio
4. Working capital to monthly expense ratio
5. Long term debt to equity ratio

APPENDIX C

Table C-1: Confidence Intervals—Quality Assurance Programs and Periodic Assessments

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Percentage of grantees that reported not maintaining a written quality assurance program	141	2.3%	0.7–7.5%
Percentage of grantees that reported conducting periodic assessments as part of their quality assurance program	139	97.1%	92.5%–98.9%
Of grantees that conducted assessments, percentage that conduct assessments once a year	135	45.5%	37.2%–54.1%
Of grantees that conducted assessments, percentage that conduct assessments every 6 months	135	9.2%	5.4%–15.4%
Of grantees that conducted assessments, percentage that select patient medical records as part of the assessment	135	91.4%	85.7%–95.0%
Of grantees that reviewed patient medical records, percentage that select records randomly	121	82.1%	74.2%–88.0%
Of grantees that reviewed patient medical records, percentage that select records from certain types of patients	121	46.8%	38.1%–55.8%
Of grantees that reviewed patient medical records, percentage that review records from all health center patients	121	30.2%	22.7%–39.0%
Of grantees that reviewed patient medical records, percentage that review records from certain provider types	121	22.1%	15.6%–30.3%
Of grantees that conducted assessments, percentage that assessed health center documentation/medical records	135	82.5%	75.2%–87.9%

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Table C-1: Confidence Intervals—Quality Assurance Programs and Periodic Assessments (Continued)

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Of grantees that conducted assessments, percentage of grantees that assessed quality of care	135	82.1%	74.3%–87.9%
Of grantees that conducted assessments, percentage of grantees that assessed patient outcomes	135	61.2%	52.5%–69.2%
Of grantees that conducted assessments, percentage of grantees that assessed service trends	135	56.7%	48.0%–64.9%
Of grantees that conducted assessments, percentage of grantees that assessed the medical necessity of care	135	35.0%	27.5%–43.4%

Source: Office of Inspector General (OIG) analysis of medical record review, 2011.

Table C-2: Confidence Intervals—Of Grantees With Quality Assurance Programs, Percentage That Addressed Each Element

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Clinical protocols for diabetes screening and/or care	139	88.7%	82.1–93.1%
Clinical protocols for immunizations	139	86.9%	79.8–91.8%
Patient outcomes related to diabetes screening/care	139	91.9%	85.7–95.5%
Patient outcomes related to immunizations	139	81.4%	73.4–87.4%
Clinical protocols for hypertension screening/care	139	81.4%	73.7–87.3%
Clinical protocols for cervical cancer screening	139	80.3%	72.4–86.3%
Clinical protocols for breast cancer screening	139	79.4%	71.4–85.6%
Clinical protocols for colon cancer screening	139	79.4%	71.4–85.6%
Clinical protocols for cholesterol screening/care	139	77.2%	69.3–83.5%

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Table C-2: Confidence Intervals—Of Grantees With Quality Assurance Programs, Percentage That Addressed Each Element (Continued)

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Clinical protocols for pediatric care	139	76.8%	68.8–83.3%
Clinical protocols for dental care	139	69.0%	60.5–76.3%
Clinical protocols for prenatal care	139	63.9%	55.3–71.8%
Patient outcomes related to hypertension screening/care	139	72.8%	64.5–79.7%
Patient outcomes related to cervical cancer screening	139	68.4%	59.9–75.8%
Patient outcomes related to breast cancer screening	139	66.4%	57.9–73.9%
Patient outcomes related to cholesterol screening/care	139	66.4%	57.9–73.9%
Availability of clinical staff	139	85.8%	78.8–90.8%
Convenience of health center hours	139	84.9%	77.7–90.1%
Wait times for scheduled appointments	139	80.8%	72.9–86.8%

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Table C-2: Confidence Intervals—Of Grantees With Quality Assurance Programs, Percentage That Addressed Each Element (Continued)

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Availability of translation services	139	81.7%	74.0–87.5%
Affordability of care	139	77.2%	69.3–83.5%
Continuing education for medical staff	139	86.4%	79.3–91.3%
Verification of credentials for health center providers	139	86.4%	79.3–91.3%
Staff education on health center policies	139	84.9%	77.7–90.1%
Patient satisfaction	139	95.1%	89.3–97.8%
Internal quality-of-care reviewers	139	92.4%	86.1–96.0%
Resolution of patient complaints	139	92.2%	85.9–95.8%

Source: OIG analysis of medical record review, 2011.

Table C-3: Confidence Intervals—Medical Record Documentation

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Percentage of patient records that lacked sufficient documentation for reviewers to determine the overall appropriateness of at least one type of care	436	44.5%	39.1–49.9%
Of grantees with quality assurance programs, percentage that addressed the accuracy and completeness of patient medical records	139	89.3%	82.6–93.6%
Of grantees that conducted assessments, percentage that assessed health center documentation/medical records	135	82.5%	75.2–87.9%
Percentage of patient records that lacked sufficient documentation of vaccinations	405	44.0%	38.3–49.8%
Percentage of patient records that lacked documentation for preventive health care	399	5.3%	2.4–11.0%
Among patients aged 0–18, percentage of records that lacked sufficient documentation of vaccinations	125	17.3%	11.0–26.0%
Among patients aged 19–49, percentage of records that lacked sufficient documentation of vaccinations	163	62.5%	53.1–71.0%
Among patients aged 50 and over, percentage of records that lacked sufficient documentation of vaccinations	117	46.6%	36.1–57.4%
Percentage of patient records that lacked sufficient documentation of referrals	407	2.5%	1.2–5.3%
Among dental patients, percentage of records that lacked sufficient documentation of dental services	91	19.0%	11.1–30.5%

Source: OIG analysis of medical record review, 2011.

Table C-4: Confidence Intervals—Medical Reviewer Assessments of the Four Service Types

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Percentage of patients with adequate preventive health exams	399	68.4%	62.3–73.9%
Percentage of patients with inadequate preventive health exams	399	26.4%	21.4–32.0%
Percentage of patients with adequate vaccinations	405	36.8%	31.6–42.4%
Percentage of patients with inadequate vaccinations	405	19.2%	15.2–24.0%
Percentage of patients with adequate referrals	407	86.1%	81.7–89.6%
Percentage of patients with inadequate referrals	407	11.4%	8.1–15.7%
Percentage of dental patients with adequate dental services	91	74.2%	61.7–83.7%
Percentage of dental patients with inadequate dental services	91	6.8%	2.5–17.0%

Source: OIG analysis of medical record review, 2011.

Table C-5: Confidence Intervals—Medical Reviewer Assessments of Preventive Health Exams

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Percentage of patients who did not receive necessary preventive health exams	399	24.9%	20.1–30.4%
Percentage of adult patients who did not receive necessary preventive health exams	274	28.7%	22.6–35.8%
Percentage of pediatric patients who did not receive necessary preventive health exams	125	16.7%	10.5–25.4%
Percentage of adult patients who did not receive necessary colon cancer screening exams	279	21.3%	16.6–26.9%
Percentage of adult patients who did not receive necessary cholesterol screening exams	279	20.3%	15.4–26.4%
Percentage of pediatric patients who did not receive necessary hearing exams	124	15.6%	9.9–23.7%
Percentage of pediatric patients who did not receive necessary developmental screenings	123	14.7%	8.9–23.2%
Percentage of adult patients who did not receive necessary blood sugar level screening	280	9.6%	6.3–14.3%
Percentage of adult patients who did not receive necessary vision exams	281	7.5%	4.6–12.2%
Percentage of pediatric patients who did not receive necessary blood pressure exams	126	10.7%	5.7–19.0%
Percentage of pediatric patients who did not receive necessary vision exams	124	11.5%	6.6–19.2%

Source: OIG analysis of medical record review, 2011.

Table C-6: Confidence Intervals—Medical Reviewer Assessments of Vaccinations

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Percentage of patients who received inadequate vaccinations	405	16.7%	12.9–21.5%
Percentage of patients aged 50 and older who received inadequate vaccinations	117	23.9%	16.0–34.3%
Percentage of patients aged 19–49 who received inadequate vaccinations	163	17.1%	11.6–24.4%
Percentage of patients aged 0–18 who received inadequate vaccinations	125	10.0%	5.3–18.1%
Percentage of patients aged 50 and older who did not receive necessary influenza vaccinations	113	25.0%	17.2–34.8%
Percentage of patients aged 50 and older who did not receive necessary pneumococcal vaccinations	113	19.1%	12.0–29.1%
Percentage of patients aged 50 and older who did not receive necessary diphtheria, tetanus, pertussis vaccinations	115	16.1%	9.5–26.1%
Percentage of patients aged 19–49 who did not receive necessary influenza vaccinations	163	14.9%	9.8–21.9%
Percentage of patients aged 19–49 who did not receive necessary diphtheria, tetanus, pertussis vaccinations	162	14.0%	9.0–21.0%
Percentage of patients aged 19–49 who did not receive necessary hepatitis B vaccinations	163	4.4%	1.8–10.1%
Percentage of patients aged 0–18 who did not receive necessary influenza vaccinations	125	30.2%	20.9–41.6%
Percentage of patients aged 0–18 who did not receive necessary varicella (chicken pox) vaccinations	126	12.0%	6.6–20.8%
Percentage of patients aged 0–18 who did not receive necessary hepatitis A vaccinations	126	8.1%	4.3–14.7%

Source: OIG analysis of medical record review, 2011.

Table C-7: Confidence Intervals—Medical Reviewer Assessments of Referrals

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Percentage of patients who did not receive necessary referrals	407	9.7%	6.6–14.0%
Percentage of adult patients who did not receive necessary referrals	281	10.5%	6.8–16.0%
Percentage of pediatric patients who did not receive necessary referrals	126	7.8%	4.0–14.6%
Percentage of adult patients who did not receive necessary referrals for HIV/AIDS testing/treatment	281	8.0%	4.2–14.7%
Percentage of adult patients who did not receive necessary referrals for laboratory tests	281	5.1%	2.6–9.7%
Percentage of adult patients who did not receive necessary referrals for ophthalmology/optometry services	281	4.9%	2.6–8.9%
Percentage of adult patients who did not receive necessary referrals for nutritionist services	281	4.6%	2.4–8.6%
Percentage of adult patients who did not receive necessary referrals for health education	281	4.4%	2.4–8.1%
Percentage of pediatric patients who did not receive necessary referrals for laboratory tests	126	3.3%	1.1–9.1%
Percentage of pediatric patients who did not receive necessary referrals for hearing services	126	2.1%	0.7–6.7%

Source: OIG analysis of medical record review, 2011.

Table C-8: Confidence Interval—Medical Reviewer Assessment of Dental Services

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Percentage of dental patients who did not receive necessary dental services	91	2.0%	0.5–7.7%

Source: OIG analysis of medical record review, 2011.

Table C-9: Confidence Intervals—Oversight from the Health Resources and Services Administration

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Of grantees with quality assurance programs, percentage that reported that staff from the Health Resources and Services Administration (HRSA) reviewed their overall quality assurance program	139	93.7%	88.4–96.6%
Of grantees that conduct assessments, percentage that reported that HRSA staff reviewed their assessments	135	85.7%	78.9–90.6%

Source: OIG analysis of medical record review, 2011.

APPENDIX D

Detailed Methdology

This evaluation assessed the extent to which health centers maintained required quality assurance programs and health center patients received necessary primary health services. We also examined the Health Resources and Services Administration's (HRSA) oversight of the required primary health services provided in health centers. To examine required primary health services, we reviewed medical records for a sample of health center patients with at least two patient encounters between January 1, 2006, and December 31, 2007, including at least one encounter in the last 6 months of 2007.[59] We expected that patients with fewer visits were less likely to use the health center as a regular source of care and, therefore, would be less likely to have medical records available for review.

Data Collection and Analysis

Our sample of 448 health center patients was selected from a stratified random sample of 147 health center grantees (explained in more detail in the sample selection section below). We reviewed primary health services that would be relevant for a broad base of health center patients regardless of age, gender, or health history, in particular:

- preventive health exams,
- vaccinations,
- referrals for specialized treatment, and
- dental services.

To assess quality assurance programs, we surveyed the same sample of 147 health center grantees about their quality assurance programs. We requested information about the content of quality assurance programs and health center grantees' periodic service assessments.

Finally, to assess HRSA oversight, we held several meetings and calls with HRSA staff, including staff from the Bureau of Primary Health Care and the Office of Performance Review, to request Uniform Data System (UDS) data and to discuss UDS reporting, grant reviews, and performance reviews.

[59] Nationally, the average number of encounters per health center patient in 2007 was 3.9. *The Health Center Program: 2007 National Aggregate UDS Data*. Accessed at http://www.bphc.hrsa.gov/uds/2007data/national/nationaltable2.htm on August 11, 2010.

Sample Selection

Health Center Selection. Using HRSA data, we selected a stratified random sample of 150 health center grantees that (1) were funded in 2005, (2) still operating in 2006, and (3) had received a performance review between 2004 and 2006.[60, 61] HRSA's onsite review process for health center grantees changed after 2003. To ensure that all health centers in our sample had participated in HRSA's then-current review and oversight process, we limited our review to health centers that received a performance review. Health center grantees were stratified by the size of their patient population. One stratum consisted of the population of the 75 largest health centers, based on number of patients; we included all of the 75 largest health centers in our sample. The other stratum consisted of the remaining population of 315 health centers, from which we randomly selected 75.[62] After excluding three of the sampled health center grantees because of ongoing Office of Inspector General (OIG) investigations, we sent letters and information requests to the remaining 147 health center grantees.

Patient Selection. We requested information about patient encounters from the 147 sampled health center grantees to select a sample of patients for medical review. We sent letters to each of the sampled health center grantees to request that they provide information about patient encounters in 2006 and 2007. The letters requested that the health center grantees provide the name, identification number, and date of birth for all patients with at least one encounter, at any of their health center sites, in the last 6 months of 2007.[63] For each of these patients, we also requested the number of encounters at the health center in 2006 and, separately, in 2007. We received patient lists from 142 of the health center grantees. We used this information to select a sample of patients whose medical records we collected for review.

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[60] HRSA reported it had 1,002 health center grantees in 2006. *2006 National Aggregate UDS Data: Table 2*. Accessed at http://bphc.hrsa.gov/uds/2006data/national/nationaltable2.htm on December 7, 2010.

[61] Approximately 41 percent of health centers operating in 2006 met these criteria.

[62] The number of patients was based on 2005 UDS data.

[63] When requesting information about patients from health center grantees, we instructed them to use the definition of patient encounters included the *2007 Uniform Data System Reporting Manual*. HRSA's 2007 UDS Reporting Instructions for Section 330 Grantees defines encounters as "face-to-face contacts between a patient and a provider who exercises independent professional judgment in the provision of services to the patient. To be included as an encounter, services rendered must be documented in the patient's record." Encounters do not include large-scale efforts such as group immunizations, screening programs, or communitywide programs such as health fairs. Furthermore, the provision of laboratory tests, x-rays, immunizations, tuberculosis tests, and prescription refills are not counted as encounters if not accompanied by an additional service.

From the 142 health centers from which we received patient lists, we selected a sample of 490 patients. We used the following procedure for selecting patients with at least two health center encounters within 2 years:

- If the health center grantee was able to provide patient encounter information for 2006 and 2007, we randomly selected three patients from among all patients with at least two encounters between January 1, 2006, and December 31, 2007, including at least one encounter in the last 6 months of 2007. We selected three patients from each of 78 health center grantees that provided encounter information for a total of 234 patients.
- If the health center grantee was not able to provide patient encounter information for 2006 and 2007, we randomly selected four patients from among all patients with at least one encounter in the last 6 months of 2007. We selected an extra patient from this group of grantees to increase the likelihood that at least three patients from each health center would have been seen in the health center at least twice between January 1, 2006, and December 31, 2007, including at least one encounter in the last 6 months of 2007. We selected 4 patients from each of 64 health center grantees that did not provide encounter information, for a total of 256 patients.

Patient records. Of the 490 sampled patients, we determined that 36 were ineligible (not part of our intended target population) because their records did not document at least 2 patient encounters at the health center between January 1, 2006, and December 31, 2007, including at least 1 between July 1 and December 31, 2007. Of the 454 remaining patients, we received records for 448 (99 percent). We included 448 patient records in at least 1 of the analyses. However, we excluded a small number of patients from the overall and individual analyses if reviewer notes indicated that the health center offered services, but the services were refused by either the patient or the patient's parent. No more than seven patients were excluded from any single analysis due to patient refusals. We collected medical records for the sampled patients in September 2008, so services provided through that time could have been included in our medical review.

Medical Review of Health Center Records

We worked with a medical review contractor that contracted with three physicians and three dentists, all with current and/or prior health center experience, to review the status of primary health services among patients in four categories. Using information about patients' health status and medical history, they determined whether each patient

received necessary services.[64] We developed a medical review instrument,[65] with feedback from the medical reviewers, to assess:

- preventive health exams[66] (e.g., hearing[67] and vision exams, weight and blood pressure checks, and cholesterol screenings),
- vaccinations (e.g., polio; influenza; pneumococcal; measles, mumps, rubella; varicella (chicken pox); and diphtheria, tetanus, pertussis),
- referrals for specialized treatment (e.g., allergy, behavioral health, dermatology, HIV testing and/or treatment, health education, nephrology, nutritionist services, ophthalmology/optometry, and orthopedics), and
- dental services (e.g., dental exams, cleanings, fillings, and x-rays).

We pretested the review instrument and shared information among medical reviewers to improve the consistency of reviews. Prior to the full sample review, we selected a separate sample of grantees from which we requested a sample of patient records, to give medical reviewers an opportunity to provide feedback on the review items and to check for consistency among the reviewers. Medical reviewers reviewed the sample patient records using a draft medical review instrument. We made changes to the review instrument following the initial pretest and conducted a second pretest to give the medical reviewers an opportunity to use the instrument before the full sample review. None of the pretest patient records was included in the full sample review.

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[64] In some cases, preventive health guidelines recommend against certain patients' receiving specific services, such as a vaccination, given their health status or medical history. In these cases, medical reviewers would have determined that the status of this service was appropriate if the vaccine was not given.

[65] We developed the medical review instrument based on preventive health guidelines issued by organizations such as the U.S. Preventive Services Task Force, the American Academy of Pediatrics, and the American Diabetes Association, among other national and professional associations.

[66] The term "preventive health exams" is not listed as a required primary health service pursuant to 42 U.S.C. 254b(b)(1)(A)(i)(I) and 42 CFR § 51c.102(h) or as a supplemental health service pursuant to 42 CFR § 51c.102(j). We use this term broadly to encompass a variety of preventive health services, including screenings, examinations, and laboratory tests.

[67] Some of the health services assessed by our medical reviewers, such as hearing exams for adult patients, are not explicitly listed as required primary health services pursuant to 42 U.S.C. 254b(b)(1)(A)(i)(I) and 42 CFR § 51c.102(h) or as supplemental health services pursuant to 42 CFR § 51c.102(j). However, we included these services in our review because they have been recommended in guidance issued by national and/or professional health care associations for the general population and/or for individuals in certain age groups or with particular health conditions.

During the full sample review, a single medical reviewer made the final assessment about the services received by each health center patient. The medical review contractor distributed the patient records among the medical reviewers. We encouraged the medical reviewers to seek feedback from one another during the course of the review and instructed the medical review contractor to share any new information and guidance with all reviewers. However, the final assessment of each record was made by a single physician reviewer and/or dental reviewer, as appropriate.[68]

Using the medical review instruments, reviewers assessed the services received by patients. For each type of service (i.e., preventive health exams, vaccinations, referrals, and dental services), reviewers first assessed the adequacy of individual exams and services, such as hearing exams, polio vaccinations, referrals for allergy treatment, and dental fillings.[69] After assessing the individual exams and services within each type of service, medical reviewers made an overall assessment about the adequacy of each type of service.[70] A reviewer's assessment that services were adequate did not necessarily indicate that the health center provided these services to the patient, but rather the reviewer's judgment that, based on available documentation, the patient had at some point received care that was consistent with established guidelines and did not go without a necessary service.

Medical reviewers made overall assessments based on both the number and potential consequence of individual exams or services within each type of service they determined to be adequate. For example, a medical reviewer could have determined that omission of vision and blood pressure exams reflected inadequate overall preventive health services for a patient with diabetes, but not for a patient without diabetes. Reviewers generally determined that services were inadequate if, based on their judgment:

- services needed by the patient were not offered,

[68] Only those records that contained documentation of dental services at the health center were distributed among the dental reviewers.

[69] On the medical review instrument, when assessing each of the individual preventive health exams, vaccinations, referrals, and dental services, reviewers determined whether services were "appropriate," "inappropriate" or, because of the patients' age or gender, "not applicable." On the medical review instrument, inappropriate services were those that, in their judgment, were inadequate based on the patients' history and health status. Reviewers also indicated whether they could not determine the appropriateness of individual services generally, because documentation in the patient's record was incomplete.

[70] On the medical review instrument, reviewers indicated whether, overall, each type of service was "appropriate" or "inappropriate." Medical reviewers determined that a type of service was "inappropriate" based on the patients' history and health status. Reviewers also indicated whether they could not determine the appropriateness of services overall because documentation in the patient's record was incomplete.

- services needed by the patient were not provided in a timely manner, or
- unnecessary services were provided to the patient.

Medical reviewers also indicated whether they were unable to determine the adequacy of individual or overall services in any of the four areas. Reviewers could not determine the adequacy of services when documentation of services received or patient health and/or risk factors was insufficient. Cases with insufficient documentation were not included in the cases determined to be either adequate or inadequate.

We directed the medical reviewers to base their judgments on their professional experience at health centers. Although we referred to established preventive health guidelines in developing the review instrument, we did not direct medical reviewers to use specific practice standards (with the exception of the Recommended Immunization Schedules issued by the Centers for Disease Control and Prevention (CDC)) to determine whether patients received necessary services. We instructed medical reviewers to be conservative in their assessments, and in the event that existing preventive health guidelines were inconsistent, to base their assessment on the least-stringent standards.

Analysis. We conducted all analyses separately for patients in different age groups. For vaccinations, we conducted separate analyses for each of the following age groups: 0–18, 19–49, and 50 and older.[71] For each of the other service types, we conducted separate analyses for pediatric patients (aged 0–18) and adult patients (aged 19 and older). The results of the medical review are projected to a subset of all health center patients.[72] Appendix C lists the confidence intervals for all medical review statistics presented in this report.

Survey of Health Center Grantees

We surveyed health center grantees and collected documentation related to their quality assurance programs between January and April 2008. We sent surveys to the 147 sampled health center grantees and received completed surveys from 141 (96 percent). The first part of our survey collected information about quality assurance programs and the periodic

[71] CDC issues separate Recommended Immunization Schedules for patients aged 0–6, 7–18, 19–49, 50–64, and 65 and up. We combined all pediatric patients into a single group and patients aged 50 and older into a single group for analysis because of the relatively small number of patients in our sample from the youngest and oldest groups.

[72] The results are projected to patients with at least two patient encounters between January 1, 2006, and December 31, 2007 (including at least one in the last 6 months of 2007), at health centers that (1) were funded in 2005, (2) still operating in 2006, and (3) had received a performance review between 2004 and 2006.

service assessments required under these programs. The survey requested that grantees respond to a series of questions about their "internal reviews of health center services." Grantees provided information about the frequency and focus of their assessments and the method of selection of medical records used during the assessments.

The second part of the survey collected information about which, if any, of a list of approximately 70 elements was addressed by grantees' quality assurance programs. We identified these elements after reviewing HRSA program requirements and expectations, materials developed by the National Association of Community Health Centers on quality assurance programs, and quality assurance documents collected from health centers during pretesting.[73, 74]

Analysis. We analyzed health center grantees' survey responses about their quality assurance programs to determine whether health center grantees:

- maintained quality assurance programs,
- conducted periodic assessments of their services,
- reviewed medical records as part of their periodic assessments, and
- included specific elements in their quality assurance programs.

Limitations

Assessments of health center services in this report are based on the professional judgment of medical reviewers. By their nature, medical reviews involve some subjectivity. Differences in training and certification could result in differences in judgment. We conducted two pretests and made modifications to the review instrument to better standardize the medical review process.

The medical review did not address health services that patients may have received from other health providers. Generally, the medical review results are based on documentation of services received or needed during encounters at health centers. In some cases, health center patients may have received services from other health providers. Unless documented

[73] National Association of Community Health Centers, *The Role of the Health Center's Board of Directors in Establishing a Quality Assurance Program*, March 2003. Accessed at http://www.nachc.com/client/documents/publications-resources/gov_3_03.pdf on August 30, 2011.

[74] Prior to our full sample data collection, we visited two health center grantees to discuss our evaluation and to request information about their quality assurance process. We also mailed our survey to and requested documentation related to quality assurance programs from five other health center grantees.

in health center records, this information was not available to medical reviewers and, therefore, not incorporated into medical reviewers' assessments of patients' receipt of services.

We did not verify survey responses concerning grantees' quality assurance programs or their scheduled or completed periodic assessments of health services. Grantees completed survey questions about the development, maintenance, and review of their quality assurance programs and their periodic assessments of health services. Features of health center grantees' quality assurance programs, such as schedules and summaries of periodic assessments, clinical guidance, and risk management practices, often were not included in the written quality assurance program documents we collected from health center grantees. Verifying information related to quality assurance programs, in many cases, would have required reviewing general policy and procedures manuals, which we did not request health center grantees to do.

APPENDIX E

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

0 7 2 6 2011

TO: Inspector General

FROM: Administrator

SUBJECT: OIG Draft Report: "Quality Assurance and Care Provided at HRSA-Funded Health Centers" (OEI-09-06-00420)

Attached is the Health Resources and Services Administration's (HRSA) response to the OIG's draft report, "Quality Assurance and Care Provided at HRSA-Funded Health Centers" (OEI-09-06-00420). If you have any questions, please contact Sandy Seaton in HRSA's Office of Federal Assistance Management at (301) 443-2432.

/S/

Mary K. Wakefield, Ph.D., R.N.

Attachment

Health Resources and Services Administration's Comments on the Office of Inspector General Draft Report "Quality Assurance and Care Provided at HRSA-Funded Health Centers" (OEI-09-06-00420)

The Health Resources and Services Administration (HRSA) is pleased to have the opportunity to comment on the draft report referenced above. HRSA believes that this report provides an opportunity to highlight the extensive ongoing quality improvement/quality assurance (QI/QA) activities HRSA has undertaken with health centers in the last 5 years.

GENERAL COMMENTS

For more than 40 years, HRSA-supported health centers have provided comprehensive, culturally competent, quality primary health care services to medically underserved communities and vulnerable populations. As the program has evolved and grown to serve almost 20 million patients annually, HRSA has continuously focused on quality assurance, quality improvement, and quality management as critical components of health centers' success. Since 2006, when the data in this report were collected, HRSA has significantly increased its focus on quality improvement through a number of initiatives and activities, building on its experience with, and an ongoing commitment to, quality improvement across the program. Some quality improvement initiatives are well-established, and others continue to evolve, but all represent crucial steps toward sustaining even greater advances in quality of care, health outcomes, and disparity reductions across all of America's health centers. Key quality improvement initiatives and activities implemented since the time of OIG's data collection process include:

- Promoting the establishment of health centers as patient-centered medical/health homes to improve access and quality, promoting the appropriate use of services, and reducing overall health care costs;
- Collecting and evaluating uniform clinical performance measures, including disparities data, from all health centers to drive improvements in patient care and outcomes;
- Supporting the adoption of Health Information Technology (HIT), including the use of certified Electronic Health Records (EHRs), telehealth, and other technologies that advance and enable quality improvement;
- Creating capacity at the state level through the HRSA-supported Primary Care Associations (PCAs) to ensure evidence-based quality improvement practices and initiatives are adapted, spread, and sustained across all health centers of varying size and resources;
- Assessing the quality and impact of health center services through various evaluations and research methods;
- Promoting a culture of patient safety to improve outcomes and mitigate adverse events, including a major HRSA-wide focus on patient safety and pharmaceutical use; and
- Cultivating federal and non-federal partnerships that support quality improvement and assurance within and across the health centers and other HRSA-funded programs.

Since the report's data were collected, HRSA has implemented several of the recommendations, with demonstrated success, through quality initiatives and technical assistance resources,[1] as well as funding opportunities targeted for health centers to implement quality improvement activities. The progress and impact health centers have made in the areas of quality, access, cost-effectiveness, and patient outcomes is well-documented in peer reviewed literature and major reports. For example, recent research highlights that:

- Uninsured health center patients were more likely than similar patients nationally to report a generalist physician visit in the past year (82 percent vs. 68 percent), have a regular source of care (96 percent vs. 60 percent), receive a mammogram in the past two years (69 percent vs. 49 percent), and receive counseling on exercise (68 percent vs. 48 percent).[2]
- Health centers are positively associated with "better primary care experiences" in comparison with similar patients nationally. There is also a positive association between seeking care in health centers and self-reported access to care for both uninsured and Medicaid patients.[3]
- Health centers providing linguistically appropriate enabling services helped patients obtain access to health care.[4]
- Health center Medicaid patients were 11 percent less likely to be inappropriately hospitalized and 19 percent less likely to visit the emergency room inappropriately than Medicaid beneficiaries who had another provider as their usual source of care.[5]
- Rural counties with a community health center site had 33 percent fewer uninsured emergency department (ED) visits per 10,000 uninsured populations than those rural counties without a health center site. Rural health center counties also had fewer ED visits for ambulatory care sensitive visits – those visits that could have been avoided through timely treatment in a primary care setting.[6]
- ED visits are higher in counties with limited access to primary care and which lack a health center. This finding is consistent with previous research literature that

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[1] For additional information on HRSA supported quality improvement activities, see:
Bureau of Primary Health Care Performance Measures:
http://bphc.hrsa.gov/policiesregulations/performancemeasures/index.html
Report to Congress: Efforts to Expand and Accelerate Health Center Program Quality Improvement: http://bphc.hrsa.gov/ftca/riskmanagement/healthcenterqualityimprovement.pdf
HRSA Patient-Centered Medical/Health Home Initiative:
http://bphc.hrsa.gov/policiesregulations/policies/pal201101.html
Health Center Accreditation: http://bphc.hrsa.gov/policiesregulations/accreditation.html
[2] Shi L., Stevens G.D., and Politzer R.M. Medical Care 2007; 45(3): 206-213.
[3] Shi L, Stevens G.D., Journal of Ambulatory Care Management 2007; 30(2): 159-170.
[4] Weir R, et al. Use of Enabling Services by Asian American, Native Hawaiian, and Other Pacific Islander Patients at 4 Community Health Centers. Am J Public Health 2010 Nov; 100(11): 2199 – 2205.
[5] Falik M. et al. Journal of Ambulatory Care Management 29, 2006.
[6] Rust George, et al. "Presence of a Community Health Center and Uninsured Emergency Department Visit Rates in Rural Counties." Journal of Rural Health, Winter 2009 25(1): 8-16.

demonstrates the effectiveness of health centers for improving access to appropriate primary care.[7]

- Health center patient rates of blood pressure control were better than rates in hospital affiliated clinics, the Veterans Affairs health system, or in commercial managed care populations.[8]

Even with these significant achievements, HRSA recognizes that there are many opportunities to maintain and improve the quality and effectiveness of health center care. Building on the recent sustained period of health center expansion as well as previous quality improvement efforts, HRSA will continue its focus on advancing health center quality and accountability in the next phase of the program's development and in concert with applicable recommendations of this report.

OIG RECOMMENDATION

Provide more specific guidance about what grantees should address in their quality assurance programs and how they should conduct their periodic assessments.
Health Center grantees must maintain required quality assurance programs and, through these quality assurance programs, periodically assess their services. However, requirements provide little detail about what quality assurance programs and assessments must address. HRSA should specify what elements should be included in quality assurance programs and, in particular, provide more guidance about how grantees conduct their periodic assessments of services. For example, HRSA could require all grantees to review records for a random sample of patients to assess the extent to which patients received required primary services as part of their assessments. HRSA, additionally, could require health centers to assess the adequacy of medical record documentation.

HRSA RESPONSE

HRSA concurs with this recommendation. HRSA is in the process of developing specific policy guidance on QI/QA plans including periodic assessments, in accordance with the related statutory requirements.[9] Additionally, HRSA strongly supports third party quality recognition as a means to promote clinical care, reduce risk, and help control per capita cost. Recognition from a national accrediting body for Patient Centered Medical Home (PCMH) or quality accreditation are excellent ways of developing and showcasing quality care processes.[10] HRSA assists health center accreditation and PCMH recognition by supporting some of the associated costs.

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[7] Hossain MM, Laditka JN. Using hospitalization for ambulatory care sensitive conditions to measure access to primary health care: an application of spatial structural equation modeling. Int J Health Geogr. 2009 Aug 28;8:51.
[8] Hicks LS. et al. Health Affairs 25, 2006.
[9] Section 330(k)(3)(C) of the Public Health Service Act.
[10] RJ Reid et al. "Patient Centered Medical Home Demonstration: A prospective, quasi-experimental, before and after evaluation." Am J Manag Care. 2009; 15(9): e71-e87.

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As of September 2011, one quarter of all health centers are accredited through the Joint Commission or the Accreditation Association of Ambulatory Health Centers. In addition, 241 health centers have applied to the HRSA's Bureau of Primary Health Care's Patient Centered Medical/Health Home Initiative, and the first 35 to enter the process have all achieved recognition through the National Committee for Quality Assurance (NCQA). HRSA is also working with the Centers for Medicare and Medicaid Services (CMS) on a Medicare Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration, which is readying 500 additional sites to enter an NCQA recognition process starting in November 2011.

In addition, in order to directly support health centers in implementing appropriate quality assurance and clinical risk management practices, HRSA provides technical assistance designed to help health centers in various areas such as integrating risk management, quality improvement, and performance excellence, as well as tracking and reporting near misses, sentinel events, and other safety issues to reduce risk and improve quality of care. To this end, in 2010, HRSA partnered with the Emergency Care Research Institute (ECRI) to provide high-quality risk management, quality assurance, and patient safety resources.[11]

OIG RECOMMENDATION

Provide more specific guidance concerning what information is required in patient records at health centers.
Incomplete medical records limit health providers' ability to determine what health services their patients need or receive. HRSA should provide explicit guidance concerning the documentation that must be maintained in all health centers records. HRSA could develop guidance based on standards issued by national or professional associations or require health center grantees to follow established standards and offer technical assistance, as appropriate.

HRSA also should continue to support health center grantees' efforts to implement electronic record systems. Medical reviewers noted that electronic health records were more organized and legible than handwritten, paper records. HRSA's support of health center grantees' transition to electronic health records, through the American Recovery and Reinvestment Act and other agency funding, may improve health centers' ability to maintain complete medical record documentation.

HRSA RESPONSE

HRSA concurs with this recommendation. HRSA fully supports the adoption of electronic health records that meet the Meaningful Use (MU) criteria and regulations established by the Department of Health and Human Services' Office of the National Coordinator for Health

[11] ECRI is an independent nonprofit organization, dedicated to providing risk management and patient safety resources for health care organizations. ECRI risk management and patient safety resources are available to HRSA-supported Health Centers and Free Clinics.

Information Technology (ONC) and CMS. The adoption of electronic systems that align with the requirements of MU will standardize the requirements of patient records, and allow for patient registries that will enable providers to pull information on their panel or sub-segments of their panel in order to analyze clinical data and trends for quality improvement purposes. HRSA's goal is for all health centers to adopt certified EHRs; and as of May 2011, 65 percent of health centers had adopted an EHR system, putting health centers ahead of the national average.[12] In addition, in fiscal year 2010, HRSA modified the Health Center Program's required clinical performance measures to align with MU measures.

In calendar year (CY) 2010, HRSA also modified its Uniform Data System (UDS) to require all health centers to report on their specific EHR activities. This reporting includes data on whether the health center has the computerized capability and/or uses the following core MU criteria: patient history and demographic information (patient problem list, changes in vital signs, weight screening/follow-up), clinical notes (patient medication and allergy lists), computerized provider order entry (details for lab and radiology tests and how orders and results are handled), electronic entry of prescriptions (drug allergy warnings/interactions/contraindications, electronic prescribing), reminders for guideline-based interventions or screening tests (smoking status and tobacco cessation intervention), electronic exchange of key clinical information among providers of care and patient authorized entities, electronic sending of notifiable diseases, electronic reporting to immunization registries, provision of electronic copy of health information to patients if requested, capacity to provide clinical visit summaries for patients, and protection of electronic health information.

The risk management technical assistance offered in partnership with ECRI, as noted previously, also contributes to this recommendation.

OIG RECOMMENDATION

Provide more specificity about the required primary health services.
Although health center requirements indicate the broad primary health services that grantees must provide, they do not include specific quality standards for these services. HRSA should provide more guidance about the services that should be received by health center patients. To ensure that patients receive necessary services, HRSA could require explicitly that health center grantees identify specific preventive health guidance or recommendations that their health care practitioners will follow. HRSA could recommend to grantees specific guidance issued by organizations and agencies such as the U.S. Preventive Services Task Force, CDC, or other national and/or professional health associations.

12 http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__adoption_and_meaningful_use/1152.

HRSA RESPONSE

HRSA concurs with this recommendation. The specific range of services that are available at a health center and their definitions may vary based on provider qualifications and licensing requirements, as well as based on the needs of the target population and/or community served. Many professional, state and/or local certifying/licensing boards require sanction levels and/or types of service based on a provider's qualifications. This national variation in scope of practice limits HRSA's ability to specify and/or require certain procedures or more detailed aspects of core primary and preventive care services. HRSA will continue to endorse the most current, nationally recognized, evidence-based clinical practice guidelines and protocols, such as those set forth by the U.S. Preventive Services Task Force.

As part of the implementation of certified EHRs (noted previously), clinical decisionmaking support software also aligns with the report's recommendation to follow the most recent primary care clinical guidelines. The required health center clinical performance measures, all of which align with measures endorsed by the National Quality Forum and defined by CMS in their MU Stage 1 measures, also serve as a strong proxy regarding how well health centers are following nationally recommended, evidence-based quality of care standards.

OIG RECOMMENDATION

Establish procedures to independently assess patients' receipt of primary health services and the adequacy of patients' records.
Although health center grantees maintain the primary responsibility for the care received by their patients, HRSA oversight should provide the agency with more information about the extent to which health center patients receive required primary health services. UDS reporting does not provide information about the services received by most health center patients. HRSA should develop a review process that would allow them to assess the primary health services received by a cross section of health center patients. This process also should assess the adequacy of medical record documentation. For example, HRSA could collect and review a representative sample of patient records to assess the extent to which patients received adequate care. HRSA, additionally, could examine the extent to which expected documentation, such as vaccination records and patient medical histories, is maintained in a sample of patient records. During reviews, HRSA also could assess the extent to which grantees implemented elements included in their quality assurance programs, in particular those related to patients' receipt of primary health services and the adequacy of medical record documentation.

HRSA RESPONSE

HRSA concurs with this recommendation. With regard to the recommendation to assess the receipt of primary health services and the adequacy of patient records, HRSA is in the process of updating its site visit protocol to add a focus on such reviews. Future site visits will involve reviews/audits of a sample of patient records, an activity which will be complemented and supported by the movement toward electronic patient records as described previously.

In addition, the Health Center Program now requires annual reporting on a core set of clinical performance measures. These required performance measures were selected to provide a balanced and comprehensive representation of health center services, identifying clinically prevalent conditions among underserved communities and populations across the life cycle. Further, the performance measures are aligned with those of national standard setting organizations, and are commonly used by insurers and health plans such as Medicare, Medicaid, and private sector health insurance to assess quality performance. The alignment of the performance measures across the UDS and health center grant applications provides grantees with the opportunity to establish quality and performance goals for their organization and patient populations, and assess their progress toward these goals over time. As the UDS continues to expand and new guidance is offered in terms of developing QI/QA plans, there will be increasing internal capacity to monitor these services and address any service gaps.

GENERAL TECHNICAL COMMENTS

The results of this study reflect the review of data and records from 2006, prior to the implementation of significant HRSA and Health Center Program Quality Initiatives. In the past 5 years many changes in internal agency resources, legislation/funding, reporting requirements, and overall growth of the health center program have taken place.

HRSA would like to clarify that the site visits it has conducted since 2009 have continued to assess and provide technical assistance on health center performance and quality. While the site visit protocol was modified in 2009 to better align with program requirements, detailed performance reviews have continued. This alignment now provides reviewers with specific guidance on assessing both program requirements and performance improvement areas, including those related to QI/QA.

HRSA would also like to highlight the performance of the program in the context of the national landscape. The comparative performance of health centers is favorable and in some cases better than many national indicators. Currently, health centers are leaders in electronic health records adoption and delivery transformation. Furthermore, health center quality of care equals and often surpasses that provided by other primary care providers. A programmatic emphasis on quality, as well as community-responsive and culturally appropriate care, has also translated into impressive reductions in health disparities for health center patients.

These achievements are even more notable given that the health center patient population is often sicker and more at risk than seen nationally. For example, in 2010, nationally nearly 93 percent of the health center patient population had incomes at or below 200 percent of the Federal Poverty Guidelines, 62 percent were racial/ethnic minorities and 38 percent of all patients were uninsured, as compared to 40 percent, 36 percent and 16 percent of the U.S. population respectively.[13]

[13] Health Center Data: Uniform Data System, 2010. National Data: U.S. Census Bureau, 2010 Current Population Reports and Current Population Survey.

The CY 2010 program data demonstrate that centers continue to provide high quality care and improve patient outcomes, while reducing disparities:

- Between 2008 and 2010 health centers saw improved birth outcomes with the percent of low birthweight babies decreasing from 7.6 percent in 2008 to 7.4 percent in 2010, which is lower than the most recent estimated national rate of 8.2 percent. In addition, the rate of entry into prenatal care in the first trimester increased from 65 percent to 69 percent between 2008 and 2010.

- Seventy-four percent of health center children received all appropriate immunizations by their 2nd birthday - up from 69 percent in 2009. Thirty-five percent of health centers met or exceeded the Healthy People 2020 goals for this measure.

- Seventy-one percent of health center patients demonstrated control over their diabetes with a hemoglobin A1c level less than or equal to nine, holding steady from the 2009 rate. Eleven percent of health centers met or exceeded the Healthy People 2020 goals for this measure.

- Approximately 63 percent of hypertensive health center patients have their blood pressure under control, also holding steady from 2009. Fifty-seven percent of health centers met or exceeded the Healthy People 2020 goals for this measure.