

**Implementing Quality Assessment and Performance
Improvement Systems in Rural Health Clinics:
Clinic and State Agency Responses**

Working Paper Series

Astrid Knott, Ph.D.
Rural Health Research Center
Division of Health Services Research and Policy

Karen Travers
BDMP/Westport

Rural Health Research Center
Division of Health Services Research and Policy
School of Public Health
University of Minnesota

August 2002

Working Paper #42

Acknowledgements: Support for this paper was provided by the Office of Rural Health Policy, Health Resources and Services Administration, PHS Grant No. CSURC0002-04.

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EXECUTIVE SUMMARY

The goal of the Rural Health Clinic (RHC) program is increased access to health care in underserved rural areas. At the same time, the RHC program encourages the use of mid-level providers, such as physician assistants, nurse practitioners, and certified nurse midwives. Clinics have to meet two basic requirements to participate in the RHC program, they have to be located in a nonurbanized area as defined by the U.S. Census Bureau and the area has to be a designated shortage area. In 2000, 3,484 clinics participated in the RHC program. Most are small clinics with less than two provider FTEs, slightly more than half are independent and the rest are provider-based and owned by hospitals, nursing homes or other entities.

The Balanced Budget Act of 1997 revised the utilization review requirement for RHCs and called for the establishment of a quality assessment and performance improvement (QAPI) program in RHCs. A proposed rule outlining the QAPI program was published by the Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), in February, 2000. The goal of this study is to assess the potential of a diverse set of Rural Health Clinics to comply with the QAPI requirements and the capacity of state agencies to provide RHCs with technical assistance in their QAPI implementation.

A telephone survey of 40 RHCs was conducted. The clinics were selected to represent independent and provider-based RHCs as well as RHCs with significant experience in the RHC program and those that had only recently become a RHC. The survey addressed RHC characteristics, the current quality assurance program at the clinic, knowledge of the proposed QAPI regulations, plans for QAPI implementation, and resources needed for implementation. In addition to the RHC survey, a telephone survey of ten State Offices of Rural Health and ten state certification agencies was conducted. These surveys covered activities with regard to RHCs, technical assistance, planned activities for QAPI implementation, survey intervals and plans for initial surveys with QAPI criteria.

RHCs currently conduct a wide range of quality assessment (QA) activities. The content of current QA programs vary between independent and provider-based RHCs. QA activities at provider-based RHCs have a customer service orientation, likely influenced by their parent organization. Most RHCs were aware of the proposed QAPI regulations. However, one third were unaware of the proposed regulations and a significant portion of those aware of the regulations were unfamiliar with the details. This indicates a need for more effective information dissemination strategies by organizations with RHC responsibilities, including fiscal intermediaries, state certification agencies and State Offices of Rural Health.

Few RHCs could provide estimates of the time and costs for the QAPI implementation, indicating that little planning for QAPI implementation has taken place. CMS estimates the information collection requirements necessitated by the QAPI program to be one hour per year for each RHC. This dramatically underestimates the required time particularly given the variation in the existing QA activities of RHCs. Planning for the QAPI implementation by RHCs has been hampered by the lack of publication of final regulations.

In the absence of final regulations, CMS advised RHCs to look at the rules for hospital QAPI programs for guidance in planning their own QAPI program. Reliance on a program not specifically designed for RHCs and the implication that RHCs would have to evaluate the applicability of the provisions of the hospital program to their situation is problematic given the limited resources and expertise with QA requirements at RHCs. The proposed QAPI program for RHCs mirrors that for hospitals and managed care organizations participating in Medicare and provides wide latitude for RHCs in identifying QA projects and applicable measures. While the flexibility of the program is commendable, it also creates challenges for RHCs since they will have to develop their own programs with little guidance. This will particularly tax small, independent RHCs. Guidance on how well current QA programs at RHCs meet the proposed QAPI requirements would be very helpful to RHCs in their planning efforts. In addition, the establishment of a clearinghouse for QAPI projects and measures to facilitate cooperation between RHCs and reduce the duplication of efforts would be beneficial.

Necessary resources for QAPI implementation identified by RHCs included further details on the requirements of the QAPI program, increased time for implementation, staff training in QA issues and technical assistance in all aspects of QA programs. Topics for staff training identified by RHCs included review of regulations and data collection and analysis methods including measurement and chart audits. RHCs also identified wide ranging technical assistance needs in the area of quality assessment including help on how to set up the QA process or how to improve the current process, manuals, and how-to guides; more information and review of regulations; and relevant software. Provider-based RHCs are more likely to have access to non-RHC staff in the QAPI implementation than independent RHCs. Few RHCs are prepared for the QAPI implementation. Substantial training needs exist and it is unclear how they will be filled.

The proposed regulation provides several potential definitions of the minimum level of effort required of RHCs in their QAPI program. Considering the limited resources of both RHCs and state certification agencies, serious consideration should be given to the amount of effort required and its impact on operations.

While most State Offices of Rural Health (SORHs) provide some support for RHCs, only limited technical assistance for RHCs can be expected from SORHs. Most SORHs provide information and links to other information and agencies but not direct technical assistance. Licensing offices primarily have regulatory responsibilities and usually are limited to providing information on regulation changes.

More information and guidance on QAPI requirements is needed to make the program a success. To make QAPI useful to RHCs, RHCs need technical assistance in all aspects of QA. Sources of technical assistance are limited particularly for independent RHCs that cannot rely on resources from their parent organization. The requirements that QAPI implementation places on small RHCs may stress already limited resources at these clinics. This could have negative effects on access to care for rural populations served by RHCs if their clinicians have to reduce patient care time, if implementation is too costly or if clinics decide to withdraw from the RHC program because of QAPI.

INTRODUCTION

The publication of the Institute of Medicine's report on medical errors (Institute of Medicine, 2000) and the second report of the Committee on Quality of Health Care in America on how to design the health care system to innovate and improve care (Institute of Medicine, 2001) have drawn a lot of attention to the issue of quality of care. Interest in the quality of health care is not limited to the reduction of medical errors. There have been efforts to include quality in health insurance and health care buying decisions, such as HEDIS and BHCAG. The Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), have made quality of care one of the focal points of its strategic plan (Health Care Financing Administration, 1998).

In the past, quality assessment and the related issue of performance measurement mainly have focused on large health care organizations, such as hospitals and managed care plans. These issues now are being expanded to include group practices, physician offices and other providers. However, performance and quality measures developed for these types of organizations cannot simply be transferred to other providers without validation. A report in support of efforts to provide information to Medicare beneficiaries in making choices between fee-for-service (FFS) Medicare and coordinated care plans found that while substantial effort has been expended to analyze the validity of data (such as the Health Plan Employer Data and Information Set (HEDIS)) for the managed care sector, very little effort has been devoted to performance measurement in the fee-for-service sector (McCall, Pope, Griggs et al., 2000). While it was technically feasible to develop performance measurement for Medicare FFS, FFS providers faced some unique challenges. One of the major issues is that internal practice information systems were found to be less comprehensive, less automated, and less useful to

performance measurement in FFS than in managed care organizations (McCall, Pope, Griggs et al., 2000).

Established by Congress in 1977 and first implemented in 1978, the Rural Health Clinic Program was one of several programs created to improve the delivery of health care services in rural areas. The Rural Health Clinics Act (P.L. 95-210) had two goals: 1) to expand the role of non-physician providers in rural primary care to increase access to primary care services and 2) to generate additional revenue to eligible rural practices to encourage continued service and outreach to a larger proportion of underserved populations, particularly Medicare and Medicaid beneficiaries (Cheh and Thompson, 1997; Krein, 1999; Travers, Ellis and Dartt, 1995).

Reflecting the increased interest in quality improvement initiatives that focus on outcomes of care (e.g. the Medicare Conditions of Participation proposed rules for hospitals and the Joint Commission on Accreditation of Healthcare Organization's ORYX program), the Balanced Budget Act of 1997 (BBA) revised the requirement for utilization review for Rural Health Clinics (RHCs). The new provision calls for RHCs to have a quality assessment and performance improvement (QAPI) program in addition to utilization review procedures (Section 4205(b), P.L. 105-33).

The implementation of the QAPI program creates a number of challenges for RHCs. The lack of useful information systems described by researchers in their evaluation of HEDIS measures for use in FFS Medicare (McCall, Pope, Griggs et al., 2000) will be magnified for RHCs, since the study conducted for CMS evaluated physician group practices with at least 50 full-time equivalent physicians while the median RHC employs less than two clinicians (Cheh and Thompson, 1997). RHCs have less resources than group practices with 50 plus physicians and problems found in group practices are likely to be compounded in RHCs. In addition, the

QAPI program is rooted in QA and performance measurement programs for hospitals. In the absence of proposed or final rules for QAPI, CMS advised RHCs to look at hospital rules for guidance (Health Care Financing Administration, 1997). RHCs were asked to adapt a program that was developed for hospitals to their situation, get familiar with the hospital program, evaluate what is and what is not relevant to their situation, and then plan and implement a QAPI program of their own making.

The implementation of QAPI in the RHC program will likely have a greater impact on the 1,899 independent RHCs than on the 1,585 provider-based RHCs. While hospitals with provider-based RHCs can lend staff and experience to their clinics to help them comply with the changes in the regulations, independent RHCs will have fewer available resources to comply with the QAPI initiative. QAPI programs will almost certainly be designed and managed – if not operated – by the clinical staff of RHCs which tend to be small. The median number of physicians, PAs, and NPs employed by a RHC is 1.8 (Cheh and Thompson, 1997). In many cases, participation in QAPI initiatives will be the first exposure that physician practices have to measuring outcomes of care. Consequently, complying with this new program requirement may stress the existing clinical resources of many freestanding Rural Health Clinics. To the extent that the change in the rules influences providers to drop out of the program, the RHC program goal of improving access to primary care services in rural areas may be compromised.

This study has three goals:

- to assess the potential of a diverse set of Rural Health Clinics to comply with the QAPI requirements,
- to assess the capacity of state agencies to provide RHCs with technical assistance in their QAPI implementation, and
- to recommend activities RHCs may undertake to comply with the new regulations.

THE QAPI PROGRAM AS OUTLINED IN THE PROPOSED RULE

The original implementation date for the QAPI provision was January 1, 1998. In December, 1997, in the absence of proposed or final regulations and with the understanding that the “requirements of the regulation will not be applied retrospectively”, CMS encouraged RHCs to “begin developing plans and the ability to carry out [the] responsibility” of assessing and improving performance outlined in the BBA (HCFA, 1997, p. 1). However, the proposed rule outlining the changes to the RHC program was not published until February, 2000 (HCFA, 2000). Final regulations have not been published as of July 2002.

The proposed rule contains three standards: (1) the components of a performance improvement program, (2) the monitoring of performance activities, and (3) the program responsibilities.

Components of the Performance Improvement Program

The proposed rule establishes that RHCs will be responsible to “carry out a performance improvement program of their own design to improve the quality of care furnished to their patients. Each clinic would have to develop, implement, maintain and evaluate an effective, data-driven QAPI program based on its own individual needs and resources. ... The program would be required to reflect the complexity of the RHC’s organization and services” (HCFA, 2000, p. 10458).

As a result of the program, RHCs should “be able to support sharing of best practices among their peers” and should achieve “demonstrable and sustained improvement in significant aspects of clinical care and nonclinical services that can be expected to affect the population served” (HCFA, 2000, p.10458). The structures and measures of implementation will not be prescribed by CMS, rather the condition for certification will focus on the expected result of the

program. CMS will move the focus of service evaluation from prescribed structures and processes to outcomes. The proposed rule describes the four key elements of each RHC's QAPI program:

1. Identification and prioritization of opportunities to improve health status and health care,
2. Interventions developed to target specific populations,
3. Documentation of results, and
4. Identification of additional opportunities to improve health status and health care.

RHCs will be required, but are not limited, to evaluate the following areas or domains:

- Clinical effectiveness (appropriateness, prevention),
- Access to care (availability and accessibility, cultural competency, emergency intervention),
- Patient satisfaction, and
- Utilization of clinic services. (Utilization review is already required of RHCs as part of the “annual evaluation.”)

Priorities for performance improvement should be based on the prevalence and severity of identified problems. The proposed rule does not contain language on the minimum level of effort but puts forth a number of proposals for the minimum level of effort for clinics that currently do not have a performance improvement program and solicits comments on this issue.

Monitoring Performance Activities

For each of the four critical areas (clinical effectiveness, access to care, patient satisfaction, utilization of clinic services), “the clinic must measure, analyze, and track aspects of performance that the clinic adopts or develops that reflect processes of care and clinic operations.

These measures must be predictive of desired outcomes or be the outcomes themselves” (HCFA, 2000, p. 10459).

A measure is defined as an “objective means of tracking performance that enables a clinic (and a surveyor) to identify the differences in performance between two points in time” (HCFA, 2000, p. 10459). CMS places no validity and reliability requirements on the measures; however, measures need to identify a start point and an end point stated in objective terms. For example, a records review might show a 40 percent vaccination rate for appropriate adult patients. The objective might be to increase the vaccination rate to 70 percent within a year. An audit after one year should document the improvement.

Program Responsibilities

The professional staff, the administration, and the governing body of a RHC are responsible for an effective QAPI and utilization assessment. The RHC needs to identify priority areas for improvement based on prevalence and severity of problems. CMS will use its survey process to assess each clinic’s success in establishing a viable QAPI program. CMS will not assess the measures themselves but rather their utility for improving the performance of the clinic. RHCs should pick measures that fit their goals and use their professional staff’s judgment “supported by nationally approved standards, practices and reviews of current professional literature” (HCFA, 2000, p. 10459).

“[T]he clinic should be able to prove with objective data that sustained improvements have taken place in (1) actual care outcomes, patient satisfaction levels, access to care; and/or (2) processes of care and clinic operations that are predictive of improved outcomes of care and satisfaction of patients” (HCFA, 2000, p.10459). Information on the QAPI program has to be available for initial certification, routine recertification, and complaint surveys.

DATA AND METHODS

To account for hypothesized differences in available resources between independent and provider-based RHCs and differences in experience with the RHC program, clinics in the following four categories were selected for a telephone survey:

- provider-based and participating in the RHC program for more than five years,
- provider-based and participating less than three years,
- independent and participating in the RHC program for more than five years, and
- independent and participating less than three years.

The age groups were chosen to distinguish between clinics that have experience with the RHC program and its requirements and clinics that have obtained RHC status more recently. Clinics that have been participating in the RHC program for more than five years are referred to as “older clinics,” while clinics participating less than three years will be referred to as “younger clinics”.

A list of all 3,484 RHCs in 45 states¹ participating in the RHC program as of April 11, 2000 was obtained from CMS. A total of 40 RHCs were selected for the survey, one RHC in each of the four categories in ten different states. To reflect potential regional differences or differences in the relationship with the respective CMS regional office, one state from each of the ten CMS regions was chosen.

States with fewer than 20 RHCs² were excluded because of the small size of the program in those states and the potential for either special treatment of RHCs or neglect of the RHC

¹ States without RHCs: Connecticut, Delaware, Maryland, Massachusetts, and New Jersey.

² Alaska, Arizona, Hawaii, Nevada, New Mexico New York, Ohio, Rhode Island, Utah, Wyoming.

program because of its limited size. States that did not have RHCs in all four study groups³ were also excluded. Because of these exclusions, no states in the regions served by the CMS regional offices in New York and Boston were included in the study. The exclusions led to a sampling frame of 31 states with 3,251 RHCs (93% of all RHCs).

States were randomly selected within their region. A total of ten study states were selected: one from each of the remaining eight CMS regions and a second state from the largest (Atlanta Regional Office) and the second largest region (Dallas Regional Office). The ten study states are: California, Idaho, Kentucky, Minnesota, Nebraska, North Carolina, Oklahoma, South Dakota, Texas, and West Virginia. Within each of the ten states, one RHC was randomly picked in each of the four categories.

In addition to the RHCs, State Offices of Rural Health (SORHs) and state certification agencies in the ten states were surveyed. Telephone surveys of RHCs, State Offices of Rural Health and state certification agencies were conducted between July and September 2000. The RHC survey covered general characteristics of the RHCs, their knowledge about the proposed QAPI rule, their implementation plans, and other issues covered by the proposed rule. State Offices of Rural Health were asked about their ongoing activities with RHCs, technical assistance they may provide and activities they were conducting or planning related to the QAPI program. State certification agencies were queried about the frequency of surveys, the role of surveyors, the consistency of staff, and plans for initial surveys with QAPI criteria. Thirty-nine RHCs, nine State Offices of Rural Health, and ten state certification agencies responded to the survey.

³ Maine, New Hampshire, Tennessee, and Vermont.

RURAL HEALTH CLINIC (RHC) SURVEY RESULTS

Characteristics of the RHCs

Of the 39 survey respondents, 16 identified themselves as independent and 23 as provider-based.⁴ The limited sample size in this study suggests that our results are not necessarily generalizable to the population of all RHCs.

The RHCs in this study differ slightly from the national RHC population, likely due to the use of stratified sampling from specific RHC categories. They have a slightly smaller physician staff (1.2 FTEs) than a national sample of RHCs (1.6 FTEs) in a study conducted by the Maine Rural Health Research Center (Gale, Coburn, and Finerfrock, 2002). They were open for fewer hours per week (38.6) than those in the national sample (42.9). The distribution between for-profit and not-for-profit providers was similar in the two studies. Provider-based RHCs are overrepresented in this study. Nationally, 54.5 percent of RHCs are independent and 45.5 percent are provider-based according to data from CMS' Online Survey Certification and Reporting (OSCAR) database.

The clinics in the sample vary dramatically in their number of annual visits, from 550 to 50,000. The average clinic had 7,547 visits in 1999, which is slightly less than the 8,760 visits found in a national survey of RHCs (National Rural Health Association, 1994). Clinics older than five years average more visits per year (9,044) than clinics younger than three years (6,129).

Clinics tend to be small (Table 1). The average clinic in the sample has 2.4 provider FTEs (physicians and mid-levels), which is slightly less than the average staffing of 2.9 provider FTEs found by Cheh and Thompson (1997).

TABLE 1
Staffing in Rural Health Clinic Sample (n=38)

	<u>Physicians</u>	<u>Mid-Level Providers</u>
	%	%
0 FTE	18.4	2.6
Less than 1 FTE	34.2	34.2
1 to less than 2 FTEs	18.4	47.4
2+ FTEs	29.0	15.8

⁴ According to CMS data, three of the 23 self-identified provider-based clinics were independent. The classification into independent and provider-based RHCs used in the following discussion is based on self-reported data.

More than half (59%) of the RHCs were owned by hospitals. Physicians as owners (13%) were a distant second, followed by corporations (8%), private individuals, counties, and other owners (5% each). One clinic was owned by a nursing home and one by a mid-level provider (3%). The largest group of RHCs in the sample were not-for-profit (49%), followed by for-profit corporations (39%) and public entities (8%). The majority of independent RHCs was for-profit (69%), while the majority of provider-based RHCs was not-for-profit. Most of the hospital owners were small (Table 2), more than half had less than 50 available beds. The mean average daily census (ADC) for the 16 hospitals for which data were available was 48.5. The large majority (86%) of hospitals that were owners of RHCs were JCAHO accredited.

As evident from the distribution of payment sources (Table 3), RHCs serve a wide range of patients with public programs (i.e. Medicare and Medicaid) accounting for over half of the visits.

Current QA Program

RHCs currently conduct a wide range of QA activities. From a list of 13 QA activities provided (Table 4), most activities were completed by at least half of all RHCs. The most popular QA activities were monitoring of immunization rates (80%), monitoring of the timeliness and appropriateness of specific tests and procedures (77%), a regular patient satisfaction survey (77%), and the monitoring of pap smear and/or mammogram rates or recall (74%). In addition to the QA activities listed, four clinics mentioned periodic chart reviews by certain diagnoses to evaluate guideline adherence. The least performed QA activities were the evaluation of the clinic's outreach efforts and the evaluation of the effectiveness of the initial assessment and treatment of emergency cases. Both activities are performed by less than half of the RHCs. However, a substantial number of clinics indicated that they are not engaged in outreach

TABLE 2**Characteristics of Hospital Owners of RHCs in Sample**

Number of Beds		Average Daily Census (ADC)	
Mean	111	Mean	48.5
Median	45	Median	12
Minimum	15	Minimum	2.5
Maximum	560	Maximum	230
Less than 50 beds	57.1%	ADC less than 50	68.7%
50-99 beds	14.3%	ADC 50-99	18.8%
100+ beds	28.6%	ADC 100+	12.5%

TABLE 3
Payment Sources for RHCs in Sample (n=33)

	% of Visits
Medicare	35.3
Medicaid	20.3
Privately insured, self-pay/uninsured	43.4
Other	1.0

TABLE 4
Current Quality Assessment Activities of RHCs in Sample (n=39)

Activity	% RHCs
Monitoring of immunization rates or schedules	79.5
Monitoring of whether needed tests, procedures, treatment and services are provided to a patient in a timely and appropriate manner	76.9
A regular patient satisfaction survey	76.9
Monitoring rates or recall for pap smears and/or mammograms	74.4
Evaluation of clinic waiting times for appointments or after arriving at the clinic	71.8
Evaluation of the clinic's accessibility to patients with special needs	71.8
Monitoring of other preventive care	71.8
Evaluation of scope of preventive services to determine if what is provided meets the needs of your patients	64.1
Evaluation of access barriers to receiving care (i.e. transportation, financial barriers, convenient hours)	59.0
Monitoring of receipt of referral letters	51.3
Evaluation of the clinic's outreach efforts	48.7
Evaluation of the effectiveness of the initial assessment and treatment of emergency cases	43.6
Other (e.g. disease guidelines, prenatal and pediatric tracking, evaluation of diabetes care)	33.3

activities and/or do not deal with emergencies. In sum, RHCs perform QA activities with a focus on mainstays such as the monitoring of immunization rates, pap smears, and mammograms, and patient satisfaction surveys.

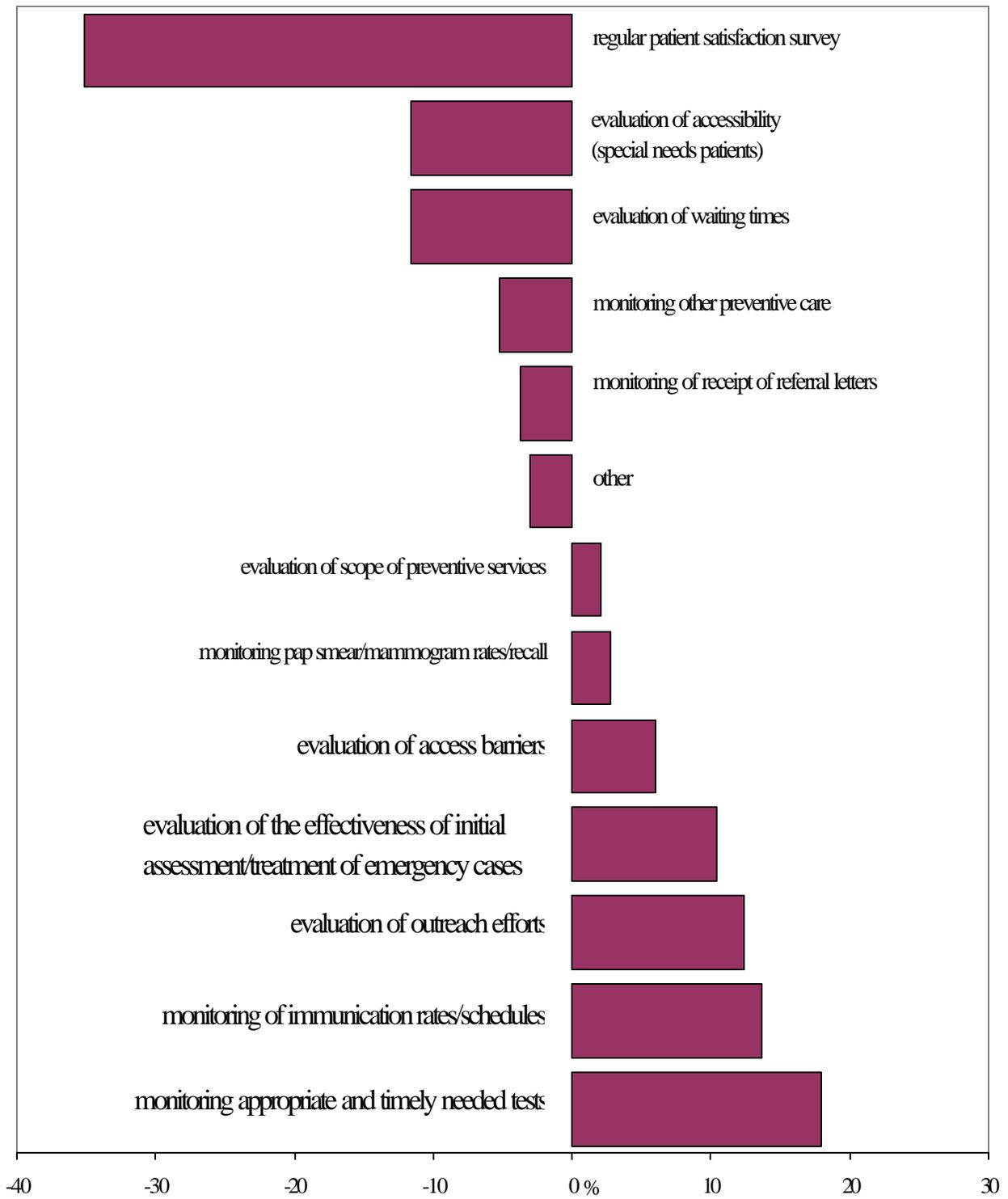
On average, clinics performed 8.2 out of the 13 tasks on the list. Older clinics performed a slightly lower number of tasks (7.9) than younger clinics (8.6). There was no difference in the number of tasks performed between independent and provider-based RHCs. However, there were differences in the content of the QA programs. QA programs at provider-based RHCs exhibit a consumer focus. The top four tasks performed by provider-based RHCs were a regular satisfaction survey, evaluation of waiting times, evaluation of accessibility, and monitoring of pap smear and/or mammogram rates and/or recall. In contrast, the top three tasks for independent clinics were monitoring of immunization rates, monitoring of the appropriateness and timeliness of tests and procedures, and monitoring of pap smear and/or mammogram rates and/or recall. The largest difference occurs for regular patient satisfaction surveys (91% of provider-based clinics compared to 56% of independent clinics (Figure 1)). This difference may be explained by the high percentage of hospital owners of RHCs accredited by JCAHO which encourages patient satisfaction surveys.

The use of problem-oriented medical records – commonly known as Subjective, Objective, Assessment Plan (SOAP) charting – attempts to improve the quality of care by making patient information easily accessible to the treating clinician. Most RHCs (87%) used problem-oriented medical records, including separate medication lists (95%) and separate problem lists (82%).

The majority of current QA programs are run by personnel with clinical training including physicians, mid-level providers, or nurses by themselves or in teams of providers

FIGURE 1

Differences in Percent of Independent and Provider-Based RHCs in Sample with Current QA Activities



(Table 5). The time RHCs currently spend on QA efforts varies widely from 0.5 hours to 80 hours per month. On average, clinics spend 15.7 hours per month on QA/QI activities. This translates into approximately one work day per FTE⁵ or 2.6 minutes per visit spent on QA activities. Independent clinics spent considerably less time on their current QA programs than provider-based clinics (9.4 vs. 19.7 hours/month). This relationship holds true when the size of the clinic (i.e. the number of FTE providers) is taken into account; independent clinics spend close to six hours per FTE per month on QA while provider-based clinics spend approximately eleven hours per FTE. Younger clinics spend more time on QA than older clinics, both on a per visit and a per FTE basis. Provider-based RHCs may spend more time on QA due to their participation in QA activities at their parent organization and their benefit from the parent organization's resources and skills.

In summary, most RHCs perform some kind of quality assessment. However, the content of the QA programs vary widely across clinics. Differences between the programs at independent and provider-based RHCs may indicate the sharing and dissemination of QA knowledge by parent organizations and the JCAHO. The existing QA programs are directed by a wide variety of mostly clinical personnel.

QAPI Implementation – Costs, Responsibilities, and Potential Form of the Program

Two thirds of RHCs in the sample were aware of the proposed rule published in the Federal Register on February 28, 2000. RHCs received their knowledge about the proposed rule from a variety of sources (Table 6). Management or administration were mentioned most often

⁵ Includes all providers (physicians, mid-level providers, and/or nurses).

TABLE 5**Person Responsible for the Current QA Program in RHCs in Sample
(n=39)**

	%
Nurse	23.0
Physician	18.0
Clinic manager, administrator, or director	18.0
PA	12.8
NP	12.8
Team (e.g. physician and administrator; physician, nursing staff, and NP, medical director, nursing supervisor, and administrative supervisor)	10.2
Quality improvement director	2.6
Other	2.6

TABLE 6**Primary Information Source on Proposed Rule for RHCs in Sample
(n=25)**

	%
Hospital, management organization, administration	20.0
CMS Regional Office	12.0
National Association of RHCs (NARHC)	12.0
State Association of RHCs	12.0
State Office of Rural Health	12.0
Other	12.0
Consultants	8.0
Federal Register	8.0
State Medical Association	4.0

followed by CMS Regional Offices, the National Association of RHCs, state associations of RHCs and State Offices of Rural Health.

Few clinics could provide estimates of the additional staff time and money needed to implement the proposed QAPI program. The estimates of time needed to implement QAPI ranged from 0 to 160 hours per month, the corresponding cost estimates varied between \$0 and \$35,000 per year.⁶ For the 17 RHCs that provided non-zero estimates, the mean costs of the QAPI implementation were \$1.64 per visit with a range from \$.09/visit to \$11.67/visit. These costs may represent significant increases in the cost per visit for some RHCs.⁷

A broad range of clinical personnel – NPs, PAs, and/or physicians – most likely will be responsible for the implementation of the QAPI program (Table 7). The majority of RHCs (87%) indicated that they will provide additional QA training to their staff to facilitate QAPI implementation. The topics most often mentioned for training were review of the regulations, and data collection and analysis methods, including measurement and chart audit. Also mentioned were documentation procedures and benchmarking indicators.

Two thirds of RHCs reported they would work together with other health care providers to implement the QAPI program. Given a number of choices regarding the form of cooperation, 16 of 26 RHCs reported they would look to other RHCs for best practices, 14 would communicate with other RHCs about their QAPI program, and 12 would establish joint efforts

⁶ RHCs indicating zero costs and no time for the QAPI implementation assume that their current QA activities fulfill the requirements of QAPI. Four 4 RHCs indicated zero costs and zero hours of additional staff time and two RHCs indicated some costs but no additional staff time.

⁷ Forty-four percent of clinics had costs per visit at or above the cap, 21 percent were below the cap, five percent are exempt from the cap, and 28 percent did not provide cost information.

TABLE 7**Person Likely to be Responsible for QAPI Implementation in RHCs in Sample
(n=39)**

	%
Clinic Manager, Administrator, or Director	23.1
Nurse	18.0
PA	12.8
Quality Assurance/Quality Improvement Staff	10.3
NP	10.3
Physician	7.7
Physician and someone else	7.7
Other (e.g. medical technologist, utilization review personnel at the hospital)	5.1
Need to hire	2.5
Don't know	2.5

with other health care providers to defray the costs of QAPI implementation. Clinics also mentioned the sharing of ideas and data as cooperation strategies.

Asked whether any non-RHC staff would be involved in implementing the QAPI program, two thirds of RHCs indicated that they anticipate using one or more types of non-RHC staff (Table 8). While 93 percent of provider-based RHCs anticipate using non-RHC staff, only 31 percent of independent RHCs did. The differences in access to outside help between independent and provider-based RHCs also is reflected in 78 percent of provider-based RHCs reporting they will use hospital staff compared to 13 percent of independent RHCs.

Ninety-five percent of the clinics surveyed indicated they needed more information on the required QAPI program prior to implementation (Table 9). The clinics reported needing an extended implementation period and technical assistance and training in QA techniques, including the choice of quality measures, identifying critical areas, data collection and measurement.

In addition to the contents of the staff training that will be provided, technical assistance needs are concentrated on QA issues (e.g. how to set up the QA process or how to improve the current process), manuals, and how-to guides; more information and a review of regulations; and necessary software. Professional associations, consultants, CMS and the fiscal intermediaries, SORH, networks, and hospitals, other RHCs, and other health care providers were mentioned as potential sources for technical assistance.

Within the QAPI program, RHCs will be required, but not limited, to evaluating the following domains: clinical effectiveness, patient satisfaction, and access. When asked to indicate the domain they would want to concentrate on first, clinical effectiveness was the domain of choice (41%) among RHCs, followed by patient satisfaction (31%) and access (21%).

TABLE 8
Use of Non-RHC Staff in the Implementation of QAPI
in RHC Sample*
(n=39)

	%
Hospital staff	51.3
State Office of Rural Health	23.1
Paid consultants	20.5
Network staff	18.0
State Rural Health Association	15.4
Other	5.1

*Multiple responses possible.

TABLE 9**Resources Needed to Implement the QAPI Program in RHCs in Sample
(n=37)**

	%
More information about required QAPI program	94.9
Time to implement the program	79.5
Technical assistance on choosing quality measures, identifying critical areas and data collection	61.5
Training in QA techniques and measurement	61.5
Other (e.g. funding for QA staff, benchmarks, software, evaluation of current QA program)	43.6

Two clinics (5%) said they would work on all three domains simultaneously. Twenty-six percent chose their domain of choice because they were already working on one or both of the other domains, 18 percent chose it because they considered it to be the most important or essential domain, and 18 percent chose it because they were already working on this domain.

When presented with a choice regarding the minimum level of effort, RHCs clearly favor one project per domain (82%) over the alternative of three projects per 1,000 patients (18%). RHCs prefer a standard that results in fewer required QAPI projects for the individual clinic.⁸

RHCs had a number of other concerns regarding QAPI implementation including the potential for more paperwork without an improvement in patient care, increased staffing needs outside of patient care, and an additional pull on already limited resources. RHCs are looking for ways to make QAPI useful and not just an information collection effort required by CMS.

Another issue is who would conduct audits or be responsible for evaluation since most of the clinics are small and other providers can be quite a distance away. RHCs question the value of self-evaluation in small clinics. They also wanted to know whether their current QA activities would meet the QAPI standards.

STATE OFFICES OF RURAL HEALTH SURVEY RESULTS

Nine of the ten State Offices of Rural Health (SORH) contacted completed the telephone survey. The nine State Offices of Rural Health rate their state's environment for Rural Health Clinics as very supportive (average of 4.2 on a scale of 1-not supportive to 5-extremely

⁸ Only a small number of RHCs (n=14) were able to provide the annual number of patients. These data are not routinely collected for billing or other purposes. The 14 clinics that reported data had patient volumes ranging from 315 to 6,000 annually with an average of approximately 2,000 (median 1,300). For the average clinic, the first standard (one project per domain) requires three projects, while the second standard (three projects per 1,000 patients) would require six projects. Clinics clearly prefer the standard that would result in fewer mandatory projects.

supportive). Seven State Offices of Rural Health provide assistance to RHCs, such as community assessments, technical assistance in the application process, and/or training for grant writing. Three State Offices of Rural Health provide funding to selected RHCs. One of the State Offices of Rural Health supports only those RHCs that are funded by the SORH.

Four State Offices of Rural Health function as a source of information for RHCs. Six inform RHCs about relevant proposed and/or final regulations. Of these, four have a regular information flow to RHCs, such as a newsletter or a regular mailing, and two inform RHCs as issues arise. However, one third of RHCs were unaware of the proposed rule and a significant portion of those aware of the rule were unfamiliar with its details.

At the time of the survey (at least four months after publication of the proposed QAPI rule), four State Offices of Rural Health had launched an activity regarding the proposed QAPI rule. The main goal of these activities was to inform the RHCs about the impending new requirements. One State Office of Rural Health had recently hired a staff person to deal with health care quality issues, although the hiring was unrelated to the proposed QAPI rule.

Three State Offices of Rural Health were not planning any future support of the QAPI implementation. The other six viewed their primary role as disseminating information and providing links to resources in state government and elsewhere. However, when asked specifically about providing technical assistance to RHCs for the implementation of the QAPI program, only four said that they would do so. The potential technical assistance included “direct consultation, on-site assistance, workshops, arrangement of mentoring between RHC staff, and funding for outside consultants”, “phone assistance and link to information”, and technical assistance “as asked.”

Five State Offices of Rural Health were concerned about the impact of the QAPI program on small RHCs. The main concern related to the lack of resources at small RHCs which likely will hinder their implementation of the program. The small number of staff at these clinics also may undermine the meaningfulness of the QAPI program in areas such as audits. In addition to the lack of resources, the complexity and ambiguity of federal rules and regulations puts a further onus on already stressed clinics, because of the need for interpretation. While one state agency suggested that more specific guidelines would be helpful to RHCs by eliminating uncertainty, another thought the regulations should be general enough to allow adaptation to the local circumstances to elevate the QAPI program beyond a certification requirement to a meaningful tool at the individual clinic level.

In summary, the State Offices of Rural Health have started activities relevant to QAPI. Given the lack of final rules and the dearth of information on the program, these activities have been mainly informational. However, SORHs were not mentioned frequently by RHCs as their primary source of information regarding the QAPI rule and a sizeable number of RHCs were unaware of the proposed regulation. The responsibility for disseminating information does not rest solely with SORHs. Licensing offices – as the enforcers of the regulations – and fiscal intermediaries or CMS are also charged with this responsibility.

RHCs may expect some technical assistance from their respective State Offices of Rural Health but the availability and scope of technical assistance will vary from state to state. RHCs cannot rely exclusively on SORHs to satisfy their technical assistance needs.

LICENSING/CERTIFICATION BUREAUS SURVEY RESULTS

Ten agencies were contacted, however, one agency indicated that it did not conduct any surveys after the initial certification.⁹ None of the other questions were asked of that state agency and it was not included in the analysis. Another agency indicated that prior to November 1999 it had not completed any RHC surveys after the initial certification surveys, but the agency provided answers to the survey questions.

The interval between RHC surveys conducted by the state certification agency varies widely from state to state and only two states survey RHCs at least every other year (see Table 10). RHCs reported the average time since the last survey as approximately two years (range 0-7 years). This underestimates the true time since the last survey since it includes 13 RHCs whose last survey was their initial certification survey.

A major determinant of the interval between surveys is funding by CMS and the priority of RHC surveys compared to surveys of other providers by state agencies. Currently, home health agencies and Critical Access Hospitals appear to have higher priority. A low priority of RHC surveys reduces the chance of being surveyed because survey funds may run out before any RHC surveys are completed.

The interval between surveys is of interest since recertification surveys likely will be the main mechanism to ensure that RHCs conform with QAPI requirements. Long intervals between surveys cast into doubt the enforcement capabilities of this mechanism and make timely interventions, if RHCs need guidance or help with the QAPI, questionable. The Medicare Payment Advisory Commission has identified infrequent surveys of facilities participating in

⁹ However, three of the four RHCs in the state in question indicated that they had been surveyed after their initial certification survey. These surveys all occurred between 1997 and 1999.

TABLE 10
Frequency of RHC Surveys after the Initial
Certification Survey
(n=10)

	Number of States
Once every year	1
Once every 2 years	1
Once every 3-5 years	3
Once every 5 or more years*	4
Never	1

* One state had just recently begun to do RHC surveys following the initial certification survey.

Medicare as a problem and renewed its recommendation “that the Congress should require the Secretary to survey at least one-third of each facility type to certify compliance with the conditions of participation” in its report on Medicare in Rural America (Medicare Payment Advisory Commission, 2001, p. 159).

As expected, the surveyors in the majority of states (78%) describe their role solely as the monitoring of compliance with the regulations. In a third of the states, surveyors also may offer some advice for compliance, provide information on where to obtain technical assistance or inform RHCs of changes in the rules and regulations of the RHC program. Four of the nine certification agencies have staff dedicated to RHC surveys (i.e. staff with expertise or experience in RHC surveys). Training of surveyors is mostly hands-on or training on the job (e.g. mentoring, internal training by experienced staff, start with one kind of provider survey and move on to others) in addition to the basic CMS surveyor training. Two certification agencies reported that the CMS surveyor training for RHC surveys had not been available to them for a long period of time until a workshop was offered in early 2000.

When asked specifically whether they provided information on proposed and final regulations to RHCs, half of the certification agencies replied they informed RHCs. All of these agencies use special mailings to inform RHCs as changes to the regulations are made.

One agency indicated there were no current certification criteria regarding quality assurance and improvement. Eight others indicated that they followed the current Conditions of Participation (COP). One state was already looking at the new criteria and its surveyors were giving RHCs tips regarding the new criteria. Certification agencies also indicated that the current survey criteria would remain in effect until a new COP is published. Enforcement of the new regulations would begin as the new and updated COP is received.

Most certification agencies indicated that guidance on the new QA regulations would be provided soon after the publication of the final rule. The exact date depends on CMS since the states have no authority on the issue. The certification agencies function mainly as distributors of the new information and indicated that the only time lag between the issuance of the guidance and the RHCs receiving the guidance would be the time it takes to duplicate and distribute the documents once they are received from CMS.

Only one certification agency had concerns regarding the implementation of the QAPI program. It was concerned about the impact of the requirements on small RHCs, the need for education and who is going to evaluate the data (especially on clinical effectiveness and prevention) collected as part of QAPI. The other eight agencies did not have any state-specific or regional concerns regarding QAPI implementation.

DISCUSSION

One third of RHCs were unaware of the proposed regulation and nearly all of the RHCs surveyed indicated that they needed more detailed information on the QAPI regulations. Most RHCs could not determine the amount of additional staff time and money needed for QAPI. This informational need may be attributed to the provisional nature of the rule and the uncertain implementation date. More than two years passed between the passage of the Balanced Budget Act of 1997 and the publication of the proposed rule and more than two years have gone by without publication of final regulations. The great need for information also may indicate a lack of resources in Rural Health Clinics that does not allow them to focus on issues that are not important in the short term.

RHCs are aware that proposed rules for QAPI implementation have been published, but the majority of clinics are unfamiliar with the details of the proposed rule. Very few clinics were

familiar enough with the proposed rule to provide an estimate of the costs of QAPI implementation indicating that minimal planning efforts have been conducted. CMS estimates the information collection requirements necessitated by the QAPI program to amount to one hour per year for each RHC (HCFA, 2000, p. 10460). This dramatically underestimates the required time particularly given the variation in the existing QA activities of RHCs.

RHCs currently have QA programs which are frequently directed by clinical personnel. The QA programs differ widely in their scope and sophistication, most likely a reflection of available resources and minimal regulatory requirements. Although RHCs are currently conducting QA activities, the majority of clinics anticipate needing technical assistance and training regarding QAPI.

It is unclear who will provide this assistance. Limited help may be expected from the SORHs. The type and scope of support RHCs can expect from their SORH varies by state, and a significant number of SORHs do not plan on providing technical assistance for QAPI implementation. While most SORHs provide services to all RHCs in their state, some limit the services to those that are funded by the SORH. RHCs should not expect help from the licensing offices in the QAPI implementation above and beyond information on the regulatory changes, survey timetables, and particulars of surveys. Licensing offices mainly have regulatory responsibilities and depend on CMS and its regional offices for information, survey priorities and funding. SORHs should be an important source of assistance to RHCs. Their efforts should be complemented by state rural health associations and primary care associations. If none of these are able to provide the necessary assistance to RHCs, RHCs will need to turn to consultants.

Surveys by state certification agencies likely are the main mechanism to ensure compliance with QAPI regulations. However, the long interval between surveys and the wide

variation in how often RHCs can expect to be surveyed by their state licensing agency calls into question the utility of licensing surveys as an enforcement mechanism for the QAPI program. This also raises the issue of fairness since spacing of surveys varies by state. RHCs are surveyed more frequently in some states than others which provides more opportunities for guidance on compliance issues as well as more opportunities for the discovery of deficiencies and potential exclusion from the program.

Another issue of interest to surveyors is the minimum level of effort required of RHCs in the QAPI program. The proposed rule does not define the minimum level of effort but describes potential definitions. Based on the limited data available from this survey, RHCs prefer the standard that results in a smaller number of required projects (one project per domain) rather than the standard that takes the number of patients a RHC sees into account (three projects per 1,000 patients). The minimum level of effort required will determine the number of QAPI projects required of an individual RHC. Since the required number of projects can vary considerably based on the standard chosen, this has the potential to influence the level of effort required by the RHC for QA as well as the level of effort required by the state certification agency in the course of recertification surveys. Considering the limited resources of both RHCs and state certification agencies, serious consideration should be given to the amount of effort required and its impact on RHC operations.

It was surprising to learn that eight licensing agencies did not have any state-specific or regional concerns regarding the QAPI implementation. This suggests that these agencies are focused on other issues at the current time. QAPI implementation and survey issues will not become an important topic until the final regulations have been published.

RHCs need more information on the QAPI program to ensure successful implementation. Provider-based clinics can draw on the resources of their parent organization. Independent clinics are especially vulnerable to increased demands on their staff, time and other resources. These issues are evident in the concerns of the majority of SORHs about the impact of QAPI on small RHCs, especially the resources available to implement QAPI and the adaptability of the regulations to the specific circumstances of individual clinics. There will be a large demand for technical assistance to implement the QAPI program which at best can partly be satisfied by state agencies. Technical assistance needs and the lack of implementation support should be addressed or access to quality RHC services may be threatened.

The stipulation that each clinic's QAPI program should reflect the complexity of the clinic's operations and CMS' lack of prescription of the measures that should be used in QAPI provide RHCs with a high degree of flexibility in developing their QAPI programs. This flexibility should work to the advantage of RHCs since it allows the design of a program that fits each individual clinic. The flexibility also presents a challenge since clinics will have to develop their own programs and cannot rely on specific guidance. This will particularly tax small clinics. CMS can help by providing guidance for RHCs that want to evaluate their current programs.

RHCs also would benefit if a clearinghouse for QAPI surveys and projects that have worked well for RHCs was established. This would minimize the duplication of effort in developing surveys and projects. A clearinghouse could be established by state RHC associations, the National Association of RHCs or SORHs.

What should RHCs do to prepare for QAPI implementation? Beyond becoming knowledgeable about the QAPI requirements, RHCs should evaluate their current QA programs and compare them to the requirements in the proposed rule. Individual practices may be doing

more QA than they realize because some activities (such as the monitoring of referral letters) may not be identified as QA. RHCs also need to identify issues in their specific practices (e.g. patients with language barriers, adult immunization rates, referral letter follow-up) that should be addressed by their QAPI program. This focus will make the QAPI program relevant to the individual practice, should provide buy-in from staff and prevent QAPI from being viewed as having limited relevance.

Projects should focus on areas that can be improved by the RHC, such as immunization rates, screening rates, preventive services and patient satisfaction with wait times. Projects do not have to involve large data collection efforts. One to three focused questions on patient satisfaction can be sufficient. Meaningful levels of response and the total number of necessary responses should be established before the data collection begins.

Patient satisfaction surveys can be completed during waiting times at the clinic. The surveys should be short, concise and easily readable. The administration of patient satisfaction surveys should take into account seasonality and weekly or monthly visit patterns. Surveys should be conducted at different times of the year rather than only once a year.

An example for an access project is the measurement of wait times for appointments. Once a month a staff person could assess how long it takes to get three different kinds of appointments (e.g. physical, acute illness, well child visit) based on the appointment book. This may be monitored over several months. Increases in wait times would signal access problems that need to be addressed.

QAPI projects should always involve feedback, even if they did not achieve their goals. Learning from the results is necessary and unsuccessful projects may provide as much insight as successful projects.

Finally, QAPI projects should be integrated into the normal operations of a clinic. Projects may be used as marketing tools. For example, a clinic can post a sign that indicates “We have found a 50 percent immunization rate for tetanus among adult patients in our practice. We are concerned about your health and would like to raise the immunization rate to 90 percent. Please support us in this effort and have your tetanus shot updated during this visit.” Another example could include the results of patient satisfaction surveys as part of job evaluations for the clinic staff (e.g. courtesy on the phone, wait times for appointments and in the office). QAPI projects can be relevant and supportive of the operations of Rural Health Clinics.

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