

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE ESRD BENEFICIARY
GRIEVANCE PROCESS**



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EXECUTIVE SUMMARY: THE ESRD BENEFICIARY GRIEVANCE PROCESS OEI-01-11-00550

WHY WE DID THIS STUDY

Over 5,000 dialysis facilities provide life-sustaining treatment to more than 340,000 End-Stage Renal Disease (ESRD) Medicare beneficiaries. Medicare regulations require that dialysis facilities implement a process for beneficiaries to file grievances without reprisal or denial of services. Beneficiaries also have the option of filing grievances with ESRD Network Organizations, which are Medicare contractors that oversee dialysis facilities. Previous Office of Inspector General work found that the ESRD beneficiary grievance process was unreliable in identifying and resolving quality-of-care concerns.

HOW WE DID THIS STUDY

We sent a questionnaire to a random sample of 150 dialysis facilities and had an 80-percent response rate. We sent a questionnaire to 17 of the 18 ESRD networks and had a 100-percent response rate. (We conducted a site visit to the 18th network, during which we pretested the questionnaire.) We also made site visits to 13 facilities and 3 networks in 5 States, where we conducted structured interviews with staff and reviewed documentation, including the facility grievance logs.

WHAT WE FOUND

Dialysis facilities have latitude in what they record as a grievance, and two-thirds of facilities recorded five or fewer grievances in 2011. The most common grievances recorded concerned the comfort or appearance of the physical environment and interactions with staff. Anonymous grievance processes can be difficult to implement, and fear of reprisal may be difficult for facilities to measure. The Centers for Medicare & Medicaid Services (CMS) has begun to require that facilities use a standardized satisfaction survey that does not assess patient fear of reprisal for filing a grievance. ESRD networks' involvement with beneficiary grievances are constrained by limited data and reporting. They analyze grievances for trends, but the database they use is of limited utility. CMS is unable to readily provide network-specific grievance and complaint data.

WHAT WE RECOMMEND

We recommend that CMS (1) define "grievance" for facilities, (2) require that facilities report grievances regularly to their respective networks, (3) provide guidance to facilities on what constitutes a robust process for anonymous grievances, (4) work with the Agency for Healthcare Research and Quality to add a question to the standardized satisfaction survey to assess ESRD beneficiaries' fear of reprisal, and (5) provide networks with better technical support for their grievance database. CMS concurred with three of our five recommendations.

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OBJECTIVE

To describe the grievance processes that dialysis facilities and End Stage Renal Disease (ESRD) Network Organizations have in place for beneficiaries.

BACKGROUND

ESRD, characterized by a permanent loss of kidney function, entitles individuals to Medicare coverage based solely on the presence of a specific medical diagnosis.¹ Most patients with ESRD rely on lengthy, uncomfortable dialysis treatment several times a week to compensate for kidney failure. Medicare pays for treatment for eligible Americans diagnosed with ESRD.² In 2009, Medicare spent \$9.2 billion on dialysis services for 340,000 ESRD beneficiaries.³

Effective oversight of dialysis facilities, including robust processes for handling beneficiary grievances, is necessary to protect the vulnerable ESRD beneficiary population. The Centers for Medicare & Medicaid Services (CMS) divides oversight between State Agencies (SAs) and ESRD Network Organizations (networks). SAs, networks, and dialysis facilities all can handle beneficiary grievances; the grievance processes of networks and facilities are the subject of this report.

Dialysis

Treatment options for ESRD include dialysis or kidney transplantation. The most common treatment is hemodialysis,⁴ in which a machine functions as an artificial kidney and pumps blood from the patient and removes toxins and excess fluid as it flows through a filter called a dialyzer. The cleansed blood is returned to the patient's body through a vein. Peritoneal dialysis is a less common method, which drains toxins and excess fluid through the abdominal cavity using the patient's natural peritoneal membrane as a filter.

More than 5,500 facilities provide dialysis to ESRD Medicare beneficiaries. The majority of facilities are freestanding (90 percent), as opposed to hospital-based units. Most facilities are for-profit (82 percent)

¹ Medicare also covers patients with amyotrophic lateral sclerosis.

² Social Security Act (SSA), § 1881(a).

³ Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy*, ch. 6, March 2011.

⁴ Government Accountability Office, *End-Stage Renal Disease: CMS Should Monitor Access to and Quality of Dialysis Care Promptly after Implementation of New Bundled Payment System*, GAO-10-295, March 2010.

and operated by a chain organization (80 percent).⁵ Almost two-thirds of facilities are operated by just two chain organizations.⁶

Oversight of Dialysis Facilities

ESRD Networks. CMS contracts with 18 ESRD Network Organizations (networks) to evaluate and resolve beneficiary grievances, identify facilities not providing appropriate medical care, and measure and improve the quality of care through quality improvement projects.⁷ Each network covers a specific geographic region.⁸ On average, networks oversee 322 facilities in their regions. The largest network has 590 facilities in its region, and the smallest has 170. Each network's staff includes clinical personnel and a medical review board with dialysis provider and beneficiary representation.⁹ CMS withholds 50 cents per patient per dialysis treatment from facilities to fund the networks. Funding for networks in 2010 was about \$28 million.¹⁰

Consumer Assessment of Healthcare Providers and Systems Survey. As of 2012, as part of CMS's quality incentive program (QIP) for dialysis facilities, facilities must use the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey to measure patient satisfaction.¹¹ Monitoring patient satisfaction can identify concerns about the care provided. The Agency for Healthcare Research and Quality (AHRQ), which developed CAHPS, recommends that a third party administer the survey.¹² Under the QIP, facilities failing to meet certain quality-of-care performance standards had their Medicare payments reduced between 0.5 and 2 percent.¹³ In December 2011, CMS announced that 30 percent

⁵ MedPAC, *Report to the Congress: Medicare Payment Policy*, ch. 6, March 2011.

⁶ Ibid. Fresenius Medical Care North America and DaVita together own 60 percent of all dialysis facilities and 70 percent of freestanding dialysis facilities.

⁷ SSA, § 1881(c) and 42 CFR § 405.2112.

⁸ The statute at SSA, § 1881(c) requires the establishment of only 17 networks, but CMS ultimately established 18. See CMS, *Medicare ESRD Network Organizations Manual*. Pub. 100-14, ch. 1, § 20.

⁹ SSA, § 1881(c)(1), 42 CFR § 405.2113, and CMS, *Medicare ESRD Network Organizations Manual*. Pub. 100-14, ch. 2, §§ 40 and 60.

¹⁰ CMS, *ESRD Network Organization Program 2010 Summary Annual Report*, p. 6.

¹¹ 76 Fed. Reg. 70228, 70269–70270 (Nov. 10, 2011).

¹² AHRQ, *Fielding the CAHPS In-Center Hemodialysis Survey*, May, 2009.

¹³ P.L. 100-275 § 153(c), which added subsection (h) to SSA, § 1881. 42 CFR § 413.177; 76 Fed. Reg. 628 (Jan. 5, 2011). The regulations set forth the QIP incentive program in general terms; the specifics can be found in the Federal Register entry. CMS determines the payment reduction on the basis of calculated facility performance scores.

of dialysis facilities would have their payments reduced in 2012 based on their QIP scores.¹⁴

Medicare Conditions for Coverage for Dialysis Facilities. Facilities must meet 16 Conditions for Coverage (CfCs) to participate in the Medicare program.¹⁵ The CfCs address topics such as patient rights, safety, and quality assessment and performance improvement.¹⁶ Each CfC includes standards that facilities must meet. For example, under the CfC for infection control is a requirement that facilities monitor staff members and ensure that they comply with aseptic techniques. SAs oversee the CfCs through onsite certification surveys of facilities.

Beneficiary Grievances

Beneficiaries can file grievances with their respective facilities, networks, or SAs. CMS has declined to define what constitutes a grievance at the facility level.¹⁷ Facilities may instead define the term for themselves. This contrasts with other parts of Medicare, such as Medicare Advantage (MA), for which CMS defines a grievance as “any complaint or dispute... expressing dissatisfaction with any aspect of an MA organization’s or provider’s operations, activities, or behavior, regardless of whether remedial action is requested.”¹⁸

Facility Processes for Handling Grievances

Facilities must implement an internal grievance procedure for beneficiaries to file oral or written grievances without reprisal or denial of services.¹⁹ Beneficiaries may file internal grievances personally, anonymously, or through a representative of the patient’s choosing.²⁰ Furthermore, the CfCs state that beneficiaries have the right to privacy and confidentiality in all aspects of treatment.²¹ Facilities must prominently display a copy of patients’ rights, including the right to file a grievance, where it can be easily seen and read by patients.²²

¹⁴ CMS could not calculate performance scores for 625 facilities because they did not meet the minimum threshold for cases. Their payments were not reduced. CMS, *CMS Announces First Results for Program to Improve Care for Dialysis Patients*, December 15, 2011. Accessed at <http://www.cms.gov> on December 15, 2011.

¹⁵ 42 CFR pt. 494.

¹⁶ CMS first issued CfCs for ESRD dialysis facilities in 1976, revising them in 2008. See 73 Fed. Reg. 20370 (April 15, 2008).

¹⁷ 73 Fed. Reg. at 20392 (April 15, 2008).

¹⁸ 42 CFR § 422.561.

¹⁹ 42 CFR § 494.180(e).

²⁰ 42 CFR § 494.70(a)(17).

²¹ 42 CFR § 494.70(a)(3).

²² 42 CFR § 494.70(c).

Facilities must inform beneficiaries of both the facility-level internal grievance process and the network- and SA-level grievance options.²³ Facilities must also measure, analyze, and track patient satisfaction and grievances as part of the CfC for quality assessment and performance improvement (QAPI).²⁴ Facilities typically track grievances in a written or electronic log.

ESRD Network Processes for Handling Grievances

Beneficiaries can also file grievances with their respective networks.²⁵ Beneficiaries do not need to first file grievances with their facilities before contacting the networks; however, CMS instructs networks to encourage beneficiaries to use the facility-level grievance process before contacting the network.²⁶ Some beneficiaries may find it difficult to approach facility staff and reach resolution at the facility level.

Networks must keep confidential the grievant's identity unless given specific permission.²⁷ When networks receive grievances, they gather information via telephone, letter, email, and onsite reviews. Networks can make referrals to Quality Improvement Organizations, Managed Care Organizations, or other such entities if the networks identify concerns those entities could more appropriately handle.²⁸ Networks immediately refer allegations to SAs and CMS when they involve a potential life-threatening situation.²⁹

If networks determine that an instance or pattern of care exists that has affected or might affect the health or well-being of one or more beneficiaries, networks can require facilities to develop and implement improvement plans. Networks monitor how facilities implement plans and expect facilities to complete the plans within 1 to 3 months. If networks determine that facilities failed to correct the problem, networks may request a revised improvement plan, refer the grievance to SAs, or recommend sanctions to CMS regional offices.³⁰

²³ 42 CFR § 494.70(a)(14)–(17).

²⁴ 42 CFR § 494.110(a)(2)(viii).

²⁵ CMS, *Medicare ESRD Network Organizations Manual*, ch. 7, § 130. Beneficiaries can also file a complaint with the network. The network complaint process is less formal than the network grievance process. The beneficiary decides whether to use the network complaint or grievance process. In this report, we use the term “grievance” to refer to both grievances and complaints at the network level.

²⁶ CMS, *Medicare ESRD Network Organizations Manual*, ch. 7, § 130.2.

²⁷ *Ibid.*, ch. 7, § 130.4.

²⁸ *Ibid.*, ch. 7, § 130.6.

²⁹ *Ibid.*, ch. 7, § 130.9.

³⁰ *Ibid.*, ch. 7, § 150.

Networks must track and process all grievances in an electronic database.³¹ Networks have recently switched to a new database as part of a larger data system migration to the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb). Facilities use CROWNWeb to submit clinical quality measures to the networks. The database that networks use to track grievances is called the Network Contact Utility. This database also includes information on other types of requests made to networks, such as facilities asking for help with noncompliant patients or beneficiaries asking for information about their dialysis care.

Previous Work

In 2000, the Office of Inspector General (OIG) found major shortcomings in the oversight of dialysis facilities.³² Oversight focused on overall quality improvement rather than enforcing minimum requirements that protect beneficiaries from harm, and it lacked coordination and accountability on the part of the networks, SAs, and facilities. The report also found that the ESRD beneficiary grievance process was unreliable in identifying and resolving quality-of-care concerns. OIG recommended that CMS hold facilities more fully accountable for the quality of care they provide and hold the networks and SAs more fully accountable for their performance in overseeing the quality of care provided by facilities. CMS generally agreed with OIG's recommendations and specifically stated that it would strengthen procedures for anonymous grievances to avoid the possibility of retaliation against patients.

METHODOLOGY

Scope

This inspection is national in scope. It examined network and facility grievance data for 2011.

Data Sources and Collection

Questionnaire for networks. We surveyed 17 of the 18 networks using an online questionnaire. (We pretested the questionnaire during a site visit to the 18th network.) The questionnaire asked about challenges that networks face in investigating grievances, how they use grievance data to identify quality improvement opportunities, and how they share facility-specific data with SAs and CMS. We conducted the survey from June–September 2012, and had a 100-percent response rate.

³¹ Ibid., ch. 7, § 130.

³² OIG, *External Quality Review of Dialysis Facilities: A Call for Greater Accountability*, OEI-01-99-00050, June 2000.

Questionnaire for dialysis facilities. We surveyed a simple random sample of 150 facilities (of the 5,571 facilities operating in 2011) using an online questionnaire. The questionnaire covered facility grievance procedures, the number of grievances that facilities received, how facilities use grievances as part of their overall QAPI efforts, and whether facilities would record hypothetical concerns as formal grievances. As part of the questionnaire, we asked facilities to provide us with copies of the survey instrument they used in 2011 to measure patient satisfaction. We conducted the survey from July–October 2012. Two facilities we attempted to contact had closed. We received responses from 120 facilities, an 80-percent response rate. Because of this response rate, our results apply to an estimated 4,457 of the 5,571 facilities in our sampling frame. See Appendix A for an analysis of nonrespondents and Appendix B for confidence intervals and point estimates for key data points from the facility questionnaire.

Site visits to dialysis facilities and networks. We conducted site visits at a purposive sample of 3 networks in 3 States and 13 facilities in 5 States. We selected the networks on the basis of geographic diversity and size of patient population, and we selected the facilities on the basis of their proximity to the networks, as well as ownership status and QIP results. At the networks and facilities, we conducted structured interviews with staff members and reviewed policies and procedures, including those for how staff members investigate beneficiary grievances. We conducted the site visits from June–August 2012.

Dialysis facility grievance logs. While onsite, we obtained the 2011 grievance logs from the 13 facilities we visited. The logs contained a total of 103 grievances.

Analysis

Questionnaires and site visits. We performed qualitative data analysis on responses from the interviews and questionnaires. For example, we reviewed the responses for common themes. We also analyzed network and facility questionnaire responses by performing frequency counts of responses.

Dialysis facility grievance logs. We abstracted and categorized the nature of each grievance and the facility’s response to it, and performed frequency counts of those categories.

Limitations

We did not independently verify the data that facilities and networks reported to us in their questionnaires. We also could not confirm whether facilities recorded all 2011 grievances in their logs; we could analyze only

the grievances that were in the logs. The conclusions we drew from our site visits are limited to the facilities and networks we visited.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Two-thirds of facilities recorded five or fewer grievances in 2011

Facilities recorded 25,032 beneficiary grievances in 2011. However, 28 percent of facilities recorded no grievances, and 38 percent recorded between one and five grievances. Because CMS does not define what a grievance is, facilities have latitude in defining what they record as a grievance; this may explain the variation across facilities in the number of reported grievances. The low number recorded in any one facility makes it difficult for a facility to analyze grievances for patterns.

CMS requires facilities to prominently display a copy of patients' rights, including the right to file a grievance, where it can be easily seen and read by patients.³³ On our site visits, we generally observed these postings in facilities' waiting areas. Furthermore, we obtained documentation from the facilities we visited detailing the information given to patients regarding facility grievance procedures. Facilities typically gave this information to patients when they began treatment.

The most common grievances that facilities recorded concerned the comfort or appearance of the physical environment and interactions with staff

About one in four grievances that facilities reported in response to our questionnaire concerned the comfort or appearance of the physical environment (see Table 1). Because dialysis patients spend so much time at facilities receiving treatment (typically three treatments per week lasting 3 to 4 hours each), the environment and comfort are of obvious importance to them. Examples of such grievances included the facility's temperature (most often, too cold), working order of televisions, and condition of dialysis treatment chairs.

Facility staff also can be the subject of grievances (17 percent of recorded grievances). Patients frequently interact with technicians, nurses, physicians, and social workers during treatment. These grievances might involve a patient reporting that he or she had been treated rudely or unfairly by staff. For example, in one facility a patient complained that the receptionist was rude, and the patient left without receiving treatment. The facility resolved the grievance by counseling that staff member on how to be more sensitive to patients' needs.

³³ 42 CFR § 494.70(c).

Another type of recorded grievances concerned quality of care. Examples of these grievances included instances of patients losing either too much or too little fluid during treatment.³⁴ In response to these grievances, facility staff and the patient’s physician would monitor the patient during treatment, and make adjustments as necessary.

Table 1: Nature of Grievances Recorded by Facilities in 2011

Nature of Grievance	Percentage of Recorded Grievances
Physical Environment	26%
Staff Interactions	17%
Scheduling	11%
Quality of Care	10%
Staff Competence	5%
Patient-to-Patient Conflicts	3%
Other	22%
Facility Could Not Categorize	6%
Total	100%

Source: OIG analysis of data from facility questionnaires, 2012.

Facilities have latitude in what they decide to record as a grievance

Although there is no expectation for any volume of grievances, the limited number that are recorded may result from the latitude that facilities have in determining what they record in their grievance logs. Because facility staff determine for themselves what to record as a grievance, it is possible that some concerns could be omitted from grievance records.

We asked facilities to provide their definitions of a grievance, and those definitions ranged from the very broad “any problem a patient has” to the more narrowly defined “a request for an investigation of a complaint about a possible risk to the health, safety, or well-being of a patient”; or “a situation where the patient is unnecessarily at high risk.” Many facilities did not offer a definition beyond that of having a process to resolve grievances; some merely defined grievance as a “patient complaint,” and others defined it as a problem that cannot be resolved quickly.

Our questionnaire provided facilities with potential concerns and asked whether the facilities would record them as grievances if they were to receive those concerns from beneficiaries. Most facilities recorded many of the concerns—particularly quality-of-care-related concerns—as formal

³⁴ Dialysis removes harmful waste, extra salt, and water from blood.

grievances. However, 20 percent of facilities reported that they would not record at least one of the following quality-of-care-related concerns: a technician is not properly cleaning dialysis machines between shifts; a nurse is being rough when connecting the patient to the dialyzer; a nurse is not changing gloves before connecting the patient to the dialysis machine. This last concern could be a violation of the CfC on infection control, but because the facility would choose not to record it as a beneficiary grievance, State surveyors may not be aware of the potential violation unless a patient contacted them or the network directly. See Table 2 for concerns that facilities would and would not record as grievances.

At the 13 facilities we visited, staff told us that they generally record grievances only when they cannot resolve the concern immediately. In four of those facilities, staff told us that beneficiaries can request that their grievances be recorded regardless of subject or severity, which can lead to the elevation of seemingly minor problems.

Table 2 – Concerns That Facilities Would and Would Not Record As Grievances

Concern	Percentage of Facilities That Would Not Record Concern as a Grievance	Percentage of Facilities That Would Record Concern as a Grievance
Technician is not properly cleaning dialysis machines between shifts	13%	87%
Nurse is rough when connecting the patient to the dialyzer	12%	88%
Nurse does not change gloves before connecting the patient to the dialysis machine	12%	88%
Staff make the patient feel unwelcome	15%	85%
Facility is too cold	24%	76%
Patient demands to move to another dialysis chair because the patient next to him/her makes him/her feel uncomfortable	23%	77%
Patient submits written request to fix the television	28%	72%

Source: OIG analysis of data from facility questionnaires, 2012.

However, in some cases, grievances are not recorded at all. For example, at one facility we visited, a beneficiary complained over several months both about quality-of-care-related issues and his comfort during treatment. The facility did not record these as grievances. These unrecorded

grievances could present a missed opportunity to analyze trends and identify opportunities to improve quality.

Facilities generally resolve grievances directly with the staff involved, rather than through systemic improvements

Facilities have a number of tools available to resolve grievances. In their survey responses, facilities told us that these tools include staff training, implementing quality improvement plans, disciplining employees, and contacting their respective networks.

However, when we examined grievance logs in the facilities we visited, we observed that most grievances are resolved by talking to the beneficiaries and specific staff directly involved in the incident. On only a few occasions—when grievances addressed broad quality-of-care issues—did facilities hold training sessions for all staff. For example, one such grievance concerned a patient who experienced painful cannulation (insertion of a needle into the venous access point). As a result, the facility trained its nursing staff on communicating with patients during difficult interactions (the log did not note whether the facility also trained staff on cannulating). Another grievance concerned one patient who felt that some staff members were not proficient in using his dialysis machine. The facility held an in-service training on proper use of the machine.

Facility staff typically tried to resolve common grievances about the physical environment, such as temperature or broken equipment, immediately, for example by adjusting the thermostat or calling in the appropriate repair people.

Furthermore, facilities' analysis of grievances rarely results in systemic improvements. About half the facilities that we visited hold monthly meetings focused on facilitywide quality and performance improvement. During these meetings, facility staff might discuss trends gleaned from grievances; however, staff told us that their grievance volume is so low that they almost never have any grievances to discuss. For grievances that staff do not record, such as issues with televisions or temperature, staff do not conduct any formal trend analysis. Instead, the facility's point person for resolving grievances tries to informally track and identify patterns.

All but 3 percent of facilities reported that they analyze grievances to identify trends, but they are unable to see an actual trend because of the low number of cases. Of the facilities that do analyze for trends, almost all look for trends related to the physical environment, specific employees, quality of care, facility procedures, and activities of specific patients, but they were able to identify trends in fewer than a third of these areas, as Table 3 shows.

Table 3: Grievances That Facilities Analyzed for Trends

Nature of Grievance	Percentage of Facilities That Analyze for Trends	Percentage of Facilities That Identified Trends
Physical environment or appearance	98%	30%
Specific employee	97%	26%
Quality of care	97%	19%
Facility procedures	96%	20%
Specific patient	94%	27%

Source: OIG analysis of data from facility questionnaires, 2012.

Anonymous grievance processes can be difficult to implement, and fear of reprisal may be difficult for facilities to measure

Almost all facilities reported that they offer methods for beneficiaries to submit grievances anonymously. Anonymous processes at facilities we visited included submission by telephone, to corporate headquarters or to a third party, and to suggestion boxes. However, 5 of the 13 facilities we visited did not offer anonymity. At these facilities, staff told us that, although they keep confidential the identity of patients who submit grievances, the patients must give their names.

Anonymous grievances can be difficult for facilities to address. For example, if a grievance concerns a particular staff interaction, it may be difficult to obtain details about the incident when staff do not know which patient was involved. One staff person told us that “an adequate resolution is usually dependent on identifying the complainant.” Ensuring anonymity is also difficult because, as facility staff told us, even when patients submit grievances anonymously, staff can often deduce the patients’ identities because of the nature of the grievances.

On the other hand, it is important that patients who file grievances feel safe from reprisals, as OIG and patient advocates have documented.³⁵ Staff at one network told us that they sometimes must stop a grievance investigation when the patient’s anonymity becomes threatened, and 13 of the 18 networks said in response to our questionnaire that when they are resolving grievances, it is a challenge to assure patients that they will not face reprisals for complaining.

³⁵ OIG, *External Quality Review of Dialysis Facilities: A Call for Greater Accountability*, OEI-01-99-00050, June 2000.

Two-thirds of the patient satisfaction surveys that facilities submitted to us include a question to measure fear of reprisals; such questions show facilities' awareness that fear of reprisal may exist. Facilities can use these data to assess how well they create an environment in which patients feel comfortable raising questions or grievances about their care.

These patient satisfaction surveys were developed by the facilities. However, as part of its QIP, CMS mandated that facilities administer the CAHPS survey to measure patient satisfaction. CAHPS includes questions that address patient satisfaction with common concerns, such as facility cleanliness, insertion of needles with as little pain as possible, and the timeliness of starting treatment. However, CAHPS does not include a question to measure a patient's fear of reprisal for lodging a grievance. Because of the time and expense involved, it is unlikely that facilities will administer both the CAHPS survey and a survey of their own. As a result, facilities may discontinue conducting their own surveys, and the chance to learn about fear of reprisal among patients will be limited.

ESRD networks' involvement with beneficiary grievances is constrained by limited data and reporting

Although the networks serve as an external option for resolving beneficiary grievances with dialysis care, that role is constrained by limited data and reporting on grievances. In addition to investigating grievances, networks also collect data and provide technical assistance to providers and beneficiaries.³⁶ We found that communication between networks and facilities primarily concerned these latter areas, not grievances. Networks communicated with facilities primarily through email reminders promoting network initiatives, such as flu vaccination, and through other educational materials. Most networks reported that they visited at least one facility in 2011, most often to provide training rather than to assist in resolving a grievance. Similarly, facilities reported that networks rarely visit them, and when networks do go onsite at a facility it is for reasons such as providing training, not to resolve grievances.

All networks analyze grievances for trends, but the database they use is of limited utility

Networks analyze grievances for trends at individual facilities and within chain organizations, as well as to identify opportunities to improve quality networkwide. All 18 networks run reports from the CMS-developed Network Contact Utility database to analyze grievances for trends. All but

³⁶ SSA, § 1881(c)(2) and 42 CFR § 405.2112. The Network areas are determined by number and concentration of beneficiaries.

two networks reported that they had developed their own programs (e.g., using Excel or SAS) to conduct additional analysis. Most networks worked to identify systemic concerns at individual facilities and opportunities for networkwide projects to improve quality.

The networks we visited raised concerns about the usefulness of the Contact Utility database for analyzing grievance data. One network reported that its understanding and use of the Contact Utility database is limited because the database lacks a data dictionary or user manual. Another network that we visited duplicated all the data from the database into its own system to more accurately and specifically categorize grievances. In doing so, this network identified a lack of historical data as a problem; because the database retains only 18 months of data, its value is limited. Furthermore, the broad categories in the database make it difficult to compare grievance trends across networks, as networks can interpret category labels differently.

Facilities rarely contact networks for assistance with grievances

Facilities rarely contact the network for assistance in dealing with grievances. Only 1 of the 13 facilities we visited had contacted its network for such help. Sixty-one percent of dialysis facilities responding to our survey said that they do not report to their respective networks the number and types of grievances they receive. Of the facilities that did, most did so only upon the network's request or on an as-needed basis, rather than on a regular basis. Only eight networks reported in our survey that they conducted an onsite investigation of a facility.

Facilities that we visited generally contacted their respective networks for assistance with difficult patients rather than for help with the grievance process. Recently, facilities have been contacting networks for assistance with the transition to CMS's CROWNWeb data system. Many of the facilities we visited voiced frustration with the transition and have often contacted their networks for help in using the new system.

CMS is unable to readily provide network-specific grievance data

We asked CMS to provide us with information on network-specific data on grievances for 2011, including the nature of grievances and their disposition. After 8 months, CMS was able to provide only high-level summary data, apparently because of the networks' inability to extract the data from the Contact Utility database. This raises questions about CMS's ability to effectively oversee the networks' role in investigating grievances.

CONCLUSION AND RECOMMENDATIONS

Medicare regulations require dialysis facilities to measure, analyze, and track beneficiary grievances. When promulgating its ESRD regulations, CMS declined to define “grievance” on the grounds that the term was “commonly understood.”³⁷ However, we found that facilities define grievances differently and as a result, they vary in how they measure and track them. Some facilities are likely not recording important, quality-of-care-related grievances, such as a nurse not changing gloves before connecting a patient to the dialysis machine, and other facilities are recording trivial grievances, such as televisions with poor reception.

This variation, coupled with facilities’ not routinely reporting their grievance data to networks, means that networks do not get an accurate, complete picture of the grievances occurring in their respective regions. Furthermore, limitations with networks’ own data make it difficult for them to conduct their own analyses of grievance data.

Therefore, we recommend that CMS:

Define “grievance” for facilities

CMS could offer a strict definition of a grievance. Alternatively, it could define a grievance in terms of what facilities would be required to record in their logs. For example, CMS could require facilities to record only those grievances related to quality of care or staff interactions, rather than grievances related to temperature or broken television sets. CMS could work with the networks to create a definition.

Provide guidance to facilities on what constitutes a robust process for anonymous grievances

CMS, either directly or via the networks, could provide facilities with guidance that explains the difference between a confidential process and an anonymous process. Networks could also offer facilities guidance on effective strategies for investigating a grievance when the beneficiary chooses to remain anonymous.

Require facilities to report grievances regularly to their respective networks

CMS already requires facilities to regularly report certain clinical data to their respective networks. As part of this reporting, CMS could require facilities to periodically provide a summary of grievances. For example, facilities could send quarterly reports to their networks with the number and nature of any grievances the facilities recorded. CMS, together with

³⁷ 73 Fed. Reg. at 20392 (April 15, 2008).

the networks, could define which types of grievances facilities could report, omitting grievances concerning broken television sets and focusing on more serious concerns related to quality of care and staff interactions. Such regular reporting would give networks more data with which to analyze trends, and thus give them a better sense of the types of grievances that beneficiaries in their regions are raising with facilities.

Work with AHRQ to add a question to CAHPS to assess beneficiaries' fear of reprisal

Once facilities transition to the CAHPS survey, it is unlikely that they will also conduct their own surveys. As a result, far fewer facilities will capture data from beneficiaries regarding fear of reprisal. CMS could work with AHRQ on adding a small number of questions designed to elicit this information. CMS would then be able to better measure the extent to which ESRD beneficiaries throughout the country fear reprisal for voicing grievances about their care.

Provide networks with better technical support for the Contact Utility database

CMS could provide networks with a data dictionary and user manual detailing the elements of the database. It could also standardize for networks the definitions for types of grievances; such standardization is essential for cross-network analysis. Furthermore, CMS could add additional standard reports and more historical data to the database so that networks would not need to create their own duplicative tools for data analysis.

We understand that the entire network data system is in a state of transition as CMS implements the new CROWNWeb system. Better support to networks will ease this transition and allow networks to best use grievance data to identify concerns in their regions.

AGENCY RESPONSE AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our first, second, and fifth recommendations.

Regarding the first recommendation, CMS no longer distinguishes between grievances and complaints at the network level, and will consider proposing to define “grievance” in the ESRD CfCs during the next rulemaking cycle.

In concurring with our second recommendation, CMS references its addition of a requirement in 2008, in response to an earlier OIG report (2000), that facilities inform beneficiaries of the right to file grievances personally, anonymously, or through a representative of the beneficiary's choosing. CMS noted that the networks are responsible for ensuring that facilities are aware of this requirement, and for informing beneficiaries of their right to decide whether to begin the grievance process at the facility or network level. CMS stated that it is working with beneficiaries, families, and other stakeholders to get direct input on making the grievance system more robust. However, our report shows that some facilities either do not have an anonymous process in place, or that they do not understand what an anonymous process is. CMS notes that networks must inform beneficiaries of their right to file a grievance either at their facility or their network, although CMS’s guidance to networks encourages beneficiaries to use the facility-level grievance process before contacting the network. This policy reinforces how important it is that facilities have a robust process for anonymous grievances.

Regarding our fifth recommendation, CMS held training sessions with the networks to assist them in learning the Contact Utility database, and included a copy of the technical manual.

CMS did not concur with our third and fourth recommendations.

Regarding the third recommendation, the agency agreed that although such data may be useful, safeguards exist to ensure that grievances are resolved. For example, the CfCs require that facilities have grievance policies and procedures in place, as well as include beneficiary satisfaction and grievances as part of their QAPI activities; that networks inform beneficiaries of the network's role in receiving, reporting, resolving, and tracking patient grievances; and that State surveyors assess the QAPI program and grievance component during their onsite inspections of facilities.

Additionally, CMS stated that the recommendation did not take into account its costs and that further assessment of need and a benefit analysis would have to be performed. However, our recommendation is meant to enhance the networks' statutory responsibility to monitor facilities by providing another indicator the networks can use to identify poor performers. With respect to the benefit analysis, we invite CMS to conduct such an analysis, including its assumptions of the costs and benefits of requiring reporting of such data.

Regarding our fourth recommendation, CMS stated that it needs to consider additional costs for revising the survey, as well as the change in burden for the beneficiaries because of the increased number of survey questions. CMS is also concerned whether an ESRD beneficiary would honestly answer a question about fear of reprisal. The ESRD Network Coordinating Center is exploring ways to obtain information on patient satisfaction with grievance resolution, and CMS plans to conduct a small number of interviews with beneficiaries and will look into this issue.

OIG questions CMS's assumption that beneficiaries would not honestly answer a question about fear of reprisal on an anonymous survey administered by a third party. That assumption calls into question whether beneficiaries would answer any of the questions honestly. Furthermore, if beneficiaries are in fact too fearful to honestly answer such a question from a third party, it underscores the importance of measuring and addressing that fear.

For the full text of CMS's comments, see Appendix C.

APPENDIX A

Nonrespondent Analysis

Our findings are based on estimates made solely from data collected from sample respondents, and we did not statistically adjust our results because of any assumptions about how the nonrespondents may have answered our questions. Consequently, our results pertain to approximately 80 percent of the population of all dialysis facilities. We performed a nonresponse analysis to see if these results for 80 percent of the population might substantially differ from those of the entire population. We compared whether the respondents and nonrespondents differ in certain characteristics and examined whether the time of response affected the results.

Comparisons of Respondents and Nonrespondents

The characteristics we had available for both respondents and nonrespondents were facility type (chain or nonchain) and nonprofit status (for-profit or nonprofit). We estimated the proportion of respondents and nonrespondents with these characteristics and performed Wald Chi-Square tests of significance. We found no statistically significant differences at the 95-percent confidence level between the respondents and nonrespondents for either of these facility characteristics.

Analysis of Late Respondents

Survey researchers have found some evidence that—in general—late respondents may provide answers more similar to those that nonrespondents would have provided than to those provided by early respondents. We categorized the respondents as either “early” or “late” by whether they responded to the questionnaire within three written attempts (“early”) or only after we contacted them by telephone (“late”). We then compared estimates of early and late respondents on key survey questions, i.e., questions as to whether facilities recorded grievances, analyzed grievances for trends, or had a method for patients to complain anonymously. We found no statistically significant differences at the 95-percent confidence level between estimates by early and late respondents.

Although we found no statistically significant differences on the basis of this analysis, we cannot conclude that no differences exist. The magnitude of any potential differences is a product of both the nonresponse rate and the extent to which nonrespondents actually would have answered the questions differently from respondents. However, our results based only on responding facilities may reasonably be expected not to differ substantially from those based on all facilities in the sample.

APPENDIX B

Point Estimates and Confidence Intervals Based on the Facility Questionnaire

We calculated confidence intervals for key data points in the facility questionnaire. The sample size, point estimates, and 95-percent confidence intervals are given for each of the following:

Data Element Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Number of Grievances Recorded	120	25,032	18,370–31,695
Percentage of Facilities That Recorded No Grievances	120	28%	20%–36%
Percentage of Facilities That Recorded 1–5 Grievances	120	38%	30%–47%
Grievances Related to Physical Environment	120	26%	15%–37%
Grievances Related to Staff Interactions	120	17%	11%–23%
Grievances Related to Scheduling	120	11%	8%–13%
Grievances Related to Quality of Care	120	10%	6%–14%
Grievances Related to Staff Competence	120	5%	3%–7%
Grievances Related to Patient-to-Patient Conflicts	120	3%	1%–5%
Facility Would Record as a Grievance That Technician Is Not Cleaning Machine	120	87%	79%–92%
Facility Would Record as a Grievance That Nurse Is Rough When Connecting Patient to Machine	120	88%	81%–93%
Facility Would Record as a Grievance That Nurse Did Not Change Gloves	120	88%	81%–93%
Facility Would Record as a Grievance That Staff Makes Patient Feel Unwelcome	120	85%	77%–90%
Facility Would Record as a Grievance That Temperature Is Too Cold	120	76%	67%–83%
Facility Would Record as a Grievance Patient Request To Move Chairs	120	77%	68%–83%
Facility Would Record as a Grievance Patient Written Request To Fix TV	120	72%	64%–80%
Facilities That Analyze Grievances for Trends	120	97%	93%–99%
Facilities That Analyze for Trends About Physical Environment	117	98%	93%–100%
Facilities That Analyze for Trends About Specific Employees	117	97%	91%–99%
Facilities That Analyze for Trends About Quality of Care	117	97%	91%–99%
Facilities That Analyze for Trends About Procedures	117	96%	90%–98%
Facilities That Analyze for Trends About Specific Patients	117	94%	88%–97%
Facility Identified Trends About Physical Environment	117	30%	22%–38%
Facility Identified Trends About Specific Employees	117	26%	18%–34%
Facility Identified Trends About Quality of Care	117	19%	13%–27%
Facility Identified Trends About Procedures	117	20%	13%–28%
Facility Identified Trends About Specific Patients	117	27%	19%–35%

Source: OIG analysis of facility questionnaire data, 2012.

APPENDIX C

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: OCT 30 2013

TO: Daniel R. Levinson
Inspector General

FROM: ~~Marilyn Tavenner~~ /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: The ESRD Beneficiary
Grievance Process (OEI-01-11-00550)

Thank you for the opportunity to review and comment on the above subject OIG draft report. The Centers for Medicare & Medicaid Services (CMS) appreciates the recommendations for improving the End Stage Renal Disease (ESRD) Beneficiary grievance process and views this report as a means to reassess progress, and to highlight recent changes we have implemented to improve the ESRD Network grievance process and to improve dialysis care. OIG's objective for this study was to describe the grievance processes that dialysis facilities and ESRD Network Organizations have in place for beneficiaries.

The investigation and resolution of grievances is an opportunity to focus on meeting the needs of ESRD patients and to create change by listening to, and learning from, the patient's perspective. In January 2013, CMS implemented a redesigned ESRD Network Statement of Work (SOW) to improve alignment with the Department of Health and Human Services National Quality Strategy and the three aims of better health, better care, and lower costs. The new approach facilitates a heightened focus on patient and family centered concerns and aims to promote better access to care.

The OIG recommendations and CMS responses to those recommendations are provided below.

OIG Recommendation

The OIG recommends that CMS define "grievances" for facilities.

CMS Response

The CMS concurs with the recommendation. CMS was already in the process of implementing a standard definition prior to this review. The ESRD Network is responsible for using standardized procedures to collect data and address grievances to promote consistency. The Networks now adhere to the definition of grievances and the grievance resolution processes described in the revised Chapter 9, "Grievances and Patient-Appropriate Access to Care," of the

Medicare ESRD Network Organizations Manual (ESRD Network Manual), and embedded in the newly deployed Patient Contact Utility. CMS has eliminated the separation of complaints and grievances and the two respective methods for resolution. The revised patient-centered grievance definition supports the premise that any instance of care that did not meet the grievant's expectations with respect to safety, civility, and/or clinical standards of care needs to be investigated and resolved. A key change to the revised definition of a grievance is that the grievant determines what constitutes a grievance. Networks have started sharing the new definition and process with the facilities in their geographic regions. In addition, the preamble to the Conditions for Coverage (CfCs) explains that a "grievance" is a commonly understood term. We will, however, consider proposing to add a "grievance" definition to the ESRD CfCs during the next rulemaking cycle, which updates these conditions, and solicit public comment.

OIG Recommendation

The OIG recommends that CMS provide guidance to facilities on what constitutes a robust anonymous grievance process.

CMS Response

The CMS concurs with this recommendation. We will continue to explore how to best meet the intent of this recommendation. As a result of OIG's recommendations provided in the June 2000 report entitled, "External Review of Dialysis Facilities – A Call for Greater Accountability" (OEI-01-00050), CMS included a requirement in the April 15, 2008 update of the 42 CFR Parts 405, 410, 413 et al. Medicare and Medicaid Programs; Conditions for Coverage for End Stage Renal Disease Facilities; Final Rule (CfCs) that facilities inform patients of the right to file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.

The Network is responsible for the following:

- Ensuring that the ESRD facilities are aware of their responsibilities, consistent with 42 CFR 494.70(c), that patients be aware that they can file grievances and that patients must be made aware of the provider's grievance procedures including the option of filing grievances anonymously.
- Informing patients of the right to decide whether to begin the grievance process at either the facility or Network level. Patients may elect to utilize the provider grievance process or directly contact the Network.

The current grievance process allows the patient, an appointed representative, family member, friend, patient advocate, an anonymous source, or any other individual to file a grievance on the patient's behalf directly with the Network in order to minimize fear of retaliation by the facility or practitioner. This protection offered to the beneficiary is further enhanced by the knowledge that their personal identifiable information is confidential unless release is authorized by the patient. The Networks currently inform an ESRD patient, or anyone filing a grievance on the patient's behalf, that any grievance case can be investigated as an anonymous grievance. Lastly,

CMS is working directly with patients and families and other stakeholders to get direct input on making the system more robust.

OIG Recommendation

The OIG recommends that CMS require facilities to report grievances regularly to their network.

CMS Response

The CMS does not concur with this recommendation. We agree this data may be potentially useful; however, there are a number of safeguards already in place to ensure that grievances are resolved. The ESRD CfCs require facilities to inform patients that they can file grievances. The CfCs also require that facilities have grievance policies and procedures in place. Additionally, the Networks are required to inform patients of the Network's role in receiving, reporting, resolving, and tracking patient grievances. The CfCs require dialysis facilities to include "patient satisfaction and grievances" as part of the scope of the Quality Assessment and Performance Improvement (QAPI) program (42 CFR 494.110 (a)). During onsite visits, state surveyors assess the QAPI program and grievance component. The patient suggestion/complaint/grievance log is reviewed with the facility staff responsible for collecting and documenting complaints and grievances. At least one patient issue is reviewed in detail as to how it was investigated and resolved, and how the result was communicated to the patient.

This recommendation does not consider the associated challenges of implementation, which include cost and allocation of resources for CMS, ESRD Network, and dialysis facility staffing and the additional resources necessary to receive, store, analyze, and implement interventions related to this new requirement. Further assessment of need and a benefit analysis would need to be performed before CMS could consider this recommendation.

OIG Recommendation

The OIG recommends that CMS work with AHRQ to add a question to CAHPS to assess beneficiary fear of reprisal.

CMS Response

The CMS does not concur with this recommendation. While we could work with AHRQ to add a small number of questions designed to capture information regarding fear of reprisal, CMS will need to consider additional costs for revising the survey as well as the change in the burden for the beneficiaries due to increasing the number of questions on the survey.

In addition to these considerations, we are concerned with whether an ESRD beneficiary would honestly answer this type of question on a patient experience survey, including a survey administered by a third party. Currently, the ESRD Network Coordinating Center at the direction of CMS, is exploring ways to obtain post-grievance resolution patient satisfaction information. We will, also, be doing a small number of cognitive interviews over the next

several months with ESRD beneficiaries and will probe on this issue. Lastly, the newly redesigned ESRD Network contract has a greater emphasis on patient and family engagement and requires that the Networks convene patient advisory councils at the local and national level. The councils will help to guide activities to decrease fear of reprisal for patients and families.

OIG Recommendation

The OIG recommends that CMS provide networks with better technical support for the Contact Utility database.

CMS Response

The CMS concurs with this recommendation. CMS has implemented OIG's recommendation and will continue ongoing support in the future. CMS has developed and deployed the Patient Contact Utility (PCU), which is a data collection utility designed to solely capture grievances, access to care issues (Involuntary Discharge, Involuntary Transfer, At Risk for Involuntary Discharge, Averted Discharge, and Failure to Place), and grievance data relevant to the updated grievance process.

The new beneficiary grievance process training sessions have been held with the Networks both prior to and post deployment. An additional eleven sessions were held that were specific to the needs of individual Networks to assist them in learning the new PCU utility. CMS included a hard copy of the technical/operations manual as part of the deployment of the PCU. All data definitions and an electronic copy of the technical manual are embedded within the PCU utility. Standard data definitions associated with the grievance process and standardized reports generated from the PCU will allow for the tracking, trending, monitoring of data, and in the development of a grievance specific Quality Improvement Activity. As part of the PCU enhancement, a centralized version will be available allowing CMS Project Officer's direct access to the PCU. This access will allow the Project Officers to provide additional support to the Networks as they continue to gain proficiency in the new utility.

The CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.

ACKNOWLEDGMENTS

This report was prepared under the direction of Joyce M. Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office; Russell Hereford, Deputy Regional Inspector General; and Kenneth Price, Deputy Regional Inspector General.

Ivan Troy served as team leader for this study. Other Office of Evaluation and Inspections staff from the Boston regional office who conducted the study include Elizabeth Havener and Kimberly Yates. Central office staff who provided support include Althea Hosein, Kevin Farber, Meghan Kearns, and Christine Moritz.

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