

Solving Patient Complaints While Avoiding Compliance Snares

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Introduction

There are four main reasons why having an effective patient grievance process is an essential part of any compliance program. First, the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation (CoP) mandate health care providers establish a patient grievance process in order to participate in the Medicare and Medicaid program. Failure to comply with CoPs may result in penalties up to and including exclusion from the Program. Second, compliance issues are often embedded in patient grievances. Providers must root out compliance issues and resolve the immediate and broader underlying issues in order to mitigate harm. Third, well-meaning attempts to resolve patient grievances, such as giving gifts or writing off co-pays, may run afoul of the anti-kickback statute. Finally, unresolved patient concerns pose a financial risk to the organization. Unhappy patients may take their business elsewhere, pursue regulatory complaint options, and/or sue.

This paper details the elements of an effective patient grievance process, while identifying compliance snares. Although the discussion focuses on the hospital patient grievance process, CMS also requires other providers such as Ambulatory Surgical Centers (ASC)ⁱ, End Stage Renal Disease (ESRD) Facilitiesⁱⁱ and Home Health Agencies (HHA)ⁱⁱⁱ to establish a patient grievance process. Elements of an effective hospital patient grievance process are relevant to other health care providers and may be adopted.

Until recently, establishing and monitoring the patient grievance process has not been a priority of many providers. Though in effect since 1999, the patient grievance CoP essentially lay dormant until CMS published the Interpretive Guidelines.^{iv} The Guidelines, effective September 19, 2005, define “grievance” and set forth timeframes by which a hospital must investigate and resolve patient grievances. The Guidelines also require hospitals to inform the patient and/or the patient’s representative of the hospital’s grievance process, including the right to file a grievance with the State agency; coordinate its existing mechanism for utilization review notice and referral to the Quality Improvement Organization (QIO) for Medicare beneficiary concerns; keep data on all complaints and grievances; and incorporate grievance data into the hospital’s Quality Improvement Process.

Last year, as part of its hospital deeming authority application, Joint Commission revised its standards and Elements of Performance (EPs) in an effort to demonstrate that they are equal to or stricter than the CMS Conditions of Participation (CoPs). As part of the standards revision process, Joint Commission significantly overhauled its patient complaint resolution standard to more closely resemble CMS Patient Grievance CoP.

In light of Joint Commission's revised standards, hospitals should expect a review of the patient grievance process during future accreditation or State Agency certification and complaint driven surveys. In preparation for upcoming surveys, providers may wish to review the patient grievance process to ensure compliance with regulatory requirements.

Elements of an Effective Grievance Process

The CMS patient grievance hospital CoP provides hospitals with unique challenges and opportunities. Hospitals must centralize the patient grievance process in order to investigate, resolve and follow up on grievances within a specified time frame. To meet the challenge, hospital staff must understand the grievance process, as well as communicate and cooperate within and between departments. A centralized grievance process provides the hospital with an opportunity to collect information about the patient experience. The information can then be analyzed and utilized to improve quality.

The checklist below provides a useful tool for monitoring the patient grievance process. While based on the Hospital patient grievance CoP, the checklist may be modified to reflect regulatory requirements specific to other providers' patient grievance process.

HOSPITAL PATIENT GRIEVANCE CHECKLIST

1.	Hospital Governing Board establishes a grievance committee.
2.	The Grievance Committee has an adequate number of qualified members to review and resolve grievances in compliance with CMS regulations.
3.	Hospital informs patients and their responsible parties of their grievance rights.
4.	Hospital establishes investigation time frames in compliance with CMS Interpretive Guidelines.
5.	Hospital develops a means of identifying patient grievances as defined by CMS Interpretive Guidelines.
6.	Hospital incorporates the Quality Improvement Organization (QIO) referral into the grievance process.
7.	Hospital establishes investigation protocols.
8.	Hospital investigates a patient's grievance in a timely manner.
9.	Hospital resolves the patient's grievance.
10.	Hospital provides a written response to the patient or representative regarding the outcome of the grievance investigation.
11.	Hospital documents its efforts to resolve the grievance and comply with CMS requirements.
12.	Hospital educates employees at every level about the grievance process.
13.	Hospital collects and analyzes data obtained through the grievance process in order to improve quality.

1. Hospital Governing Board establishes a grievance committee.

CMS requires the hospital's governing body to take full responsibility for ensuring compliance with CMS grievance process requirements. While the governing body may delegate the process to a committee, the governing body remains responsible for the committee's compliance with the grievance policy. A delegation of authority from the hospital governing body to a grievance committee must be in writing. Best practice dictates that the delegation be reflected in board minutes or a board resolution. Surveyors will likely ask to see the written delegation.

2. The Grievance Committee has an adequate number of qualified members to review and resolve grievances in compliance with CMS regulations.

CMS defines the grievance committee as being "more than one person." CMS is sending a message: The one person complaint department, common in smaller or rural hospitals, is no longer enough. An effective grievance committee requires members who possess a rare combination of substantive knowledge, investigative prowess and conflict resolution.

3. Hospital informs patients and their responsible parties of their grievance rights.

The hospital must inform the patient and/or the patient's representative of the internal grievance process, including whom to contact to file a grievance. As part of its notification of patient rights, the hospital must inform the patient that he or she may lodge a grievance with the State agency directly, regardless of whether he or she has first used the hospital's grievance process. The hospital must provide the patient or the patient's representative a phone number and address for lodging a grievance with the State agency.

4. Hospital establishes investigation time frames in compliance with CMS Interpretive Guidelines.

While CMS does not mandate specific time frames within which a hospital must review and resolve a patient's grievance, the Interpretive Guidelines offer guidance as to what CMS considers appropriate. According to the Guidelines, grievances involving situations that endanger the patient, such as neglect or abuse, should be reviewed *immediately*. Surveyors will determine whether the hospital's process assures that grievances involving situations or practices that place the patient in immediate danger are resolved in a timely manner. CMS identifies seven days as an "appropriate" timeframe by which to investigate, resolve and provide

a written response for most complaints. If the grievance will not be resolved or the investigation will not be completed within seven days, CMS states that the hospital “should inform the patient or the patient’s representative that the hospital will follow-up with a written response within a stated number of days in accordance with the hospital’s grievance policy.” In any event, CMS states that a hospital should attempt to resolve all grievances as soon as possible.

5. Hospital develops a means of identifying patient grievances as defined by CMS Interpretive Guidelines.

In order to investigate and resolve a patient grievance, a hospital must be able to identify a patient concern that fits the CMS definition of a “grievance” from one that does not. CMS’ definition of grievance is intentionally broad, incorporating all CoPs, State and Federal protections (including, but not limited to, Civil Rights and the Emergency Medical Treatment & Labor Act). Hence, it is easier to first discuss patient complaints that are not grievances.

What is NOT a patient grievance? Typically, a grievance is not a patient issue which can be resolved on the spot by staff present.

Interpretive Guidelines *define “Staff present”* as including any hospital staff present at the time of the complaint or who can quickly be at the patient’s location (i.e. nursing, administration, nursing supervisors, patient advocates, etc) to resolve the patient’s complaint.

Examples of such non-grievance issues are a request for a change of bedding, housekeeping of a room, and serving preferred food and beverage. Additionally, post-hospital verbal communications regarding patient care that would routinely have been handled by staff present, if the communication had occurred during the hospital stay, are not grievances.

A billing issue that does not involve a Medicare beneficiary is typically not a grievance.

Information obtained with a patient satisfaction survey which does not have an attached complaint typically does not meet the definition of a grievance.

What IS a grievance? The Interpretive Guidelines define a patient grievance as a written or verbal complaint by a patient, or the patient’s representative, regarding (a) the patient’s care; (b) abuse or neglect; (c) the hospital’s compliance with the CMS Hospital Conditions of Participation; or (d) a Medicare beneficiary billing complaint related to rights and limitations by 42 CFR §489.

Grievance is so broadly defined, it is best practice for a hospital to err on the side of labeling a concern a grievance. For instance, “patient care” is a broad net which captures multiple patient concerns including, but not limited to, medication administration, inadequate hygiene, delay in call light response, or lack of medical information.

Grievance is a matter of *patient* perspective. A patient’s concern, whether or not it appears legitimate on its face, is a grievance if it meets the definition set forth by CMS. Hence, if the patient perceives that she is being “neglected” or “abused,” regardless of all evidence to the contrary, her complaint is a grievance.

A verbal complaint *is* a grievance if it is not resolved at the time of the complaint, if it is postponed for later resolution, is referred to other staff for later resolution, if it requires investigation, and/or requires further action for resolution. A verbal complaint is always a grievance if it regards abuse, neglect, patient harm or hospital non-compliance with CMS requirements. This includes a situation where such a complaint is phoned into the hospital by the patient or his or representative after the patient has left the hospital.

Any issue related to Hospital Conditions of Participation (CoPs) is a grievance. Some examples of CoPs include: compliance with federal, state and local laws; patients’ rights; discharge planning; quality assessment and performance; medical staff; nursing service; medical record service; pharmaceutical services; radiological services; food and dietary.

A Medicare beneficiary’s billing issue is a grievance if it involves rights and limitations provided by 42 CFR § 498. By incorporating by reference 42 CFR § 498, CMS essentially mandates that any Medicare beneficiary billing concern is a grievance. Among other things, 42 CFR § 498 specifies basic commitments and limitations to which Medicare providers must agree as part of an agreement to provide services. This includes the limitations on allowable charges to beneficiaries for deductibles, coinsurance, copayments, and services.

If a Medicare beneficiary feels that she is being prematurely discharged from the hospital, her concern qualifies as a grievance. Medicare beneficiaries have specific rights pertaining to discharge notice and appeal.

Importantly, what first appears to be a non-grievance may actually be a grievance when two regulatory caveats are considered. First, the Interpretive Guidelines state that if an identified patient writes or attaches a written complaint on the survey and requests resolution, then the

complaint meets the definition of a grievance. If a patient writes or attaches a complaint to the survey but has not requested resolution, the hospital must treat this as a grievance if the hospital would usually treat such a complaint as a grievance.

Second, the Interpretive Guidelines state that whenever a patient or the patient's representative requests their complaint be handled as a formal complaint or grievance or when the patient requests a response from the hospital, then the complaint is a grievance and all the grievance requirements apply.

When writing policies to identify a grievance, a hospital should focus on the content of the message, not the way in which it was relayed. For instance, if the issue involves patient care, it does not matter if the concern was emailed by the patient or mentioned during a hospital phone survey.

6. Hospital incorporates the QIO referral into the grievance process.

The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control, Quality Improvement Organization. The requirement does not mandate that the hospital automatically refer each Medicare beneficiary's grievance to the QIO; however, the hospital must inform all beneficiaries of this right and comply with a request for QIO review.

7. Hospital establishes investigation protocols.

CMS requires a hospital to have policies detailing the investigative process, including the time frame for investigating, resolving and following up with the patient. While CMS does not detail the manner in which a hospital must investigate, CMS does require the hospital investigate and resolve all patients' grievances in *a prompt and consistent manner*.

A policy which details the principle steps in a grievance investigation provides the grievance committee with a template for consistent and thorough investigation. The principal steps in an investigation may include, but are not limited to: interviewing the complainant; interviewing the patient, if different from the complainant; gathering factual information through interviews with those persons having potential knowledge of the issues; identifying steps already taken to handle or resolve the concern; making observations; researching regulations, laws, and/or hospital policy and procedure; and reviewing relevant patient or hospital records.

Of course, every investigation differs depending on the type of grievance and the facts of the

case. CMS acknowledges that, while not typically the case, complaints will occasionally be complicated and require extensive investigation.

The Interpretive Guidelines state that regardless of the nature of the grievance, the hospital should make sure that it is responding to the substance of each grievance while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance.

8. Hospital investigates a patient's grievance in a timely manner.

Hospitals must investigate patient grievances in accordance with hospital policy. The policy must reflect the requirements of the CoP.

9. Hospital resolves the patient's grievance.

CMS Interpretive Guidelines indicate that most grievances should be resolved. CMS considers a grievance resolved when the patient is satisfied with the actions taken on his or her behalf. Since the patient determines whether the grievance is resolved, it is essential that the patient's desired outcome is identified during the initial interview with the patient.

Surveyors will examine how effectively the grievance process works. The Interpretive Guidelines acknowledge that there may be situations where the hospital has taken appropriate and reasonable actions on the patient's behalf in order to resolve the patient's grievance and the patient or the patient's representative remains unsatisfied with the hospital's actions. In these situations the hospital may consider the grievance closed.

In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person; the steps taken on behalf of the patient to investigate the grievance; the results of the grievance process; and the date of completion.

10. Hospital provides a written response to the patient or representative regarding the outcome of the grievance investigation.

CMS Interpretive Guidelines indicate the hospital is not required to provide an exhaustive explanation of every action the hospital has taken to investigate or resolve the grievance. However, *all* grievances require a written follow up letter.

The grievance letter should be carefully written to comply with CMS requirements while not

including statements that could be used in a legal action against the hospital. Best practice suggests having grievance letters reviewed by legal counsel in cases which are potentially compensable.

11. Hospital documents its efforts to resolve the grievances and comply with CMS requirements.

The hospital is required to document its efforts to resolve grievances and demonstrate compliance with CMS requirements. The old adage “if it’s not in writing, it didn’t happen” is particularly applicable to the hospital’s efforts to resolve a patient grievance. The documentation should provide a detailed accounting of events to show organizational compliance to surveyors during annual and complaint-driven surveys. Best practice dictates that the hospital document in a clear and concise manner: the initial grievance; steps taken to resolve the grievance; the outcome of the investigation; and the follow up letter.

12. Hospital educates employees at every level about the grievance process.

Because a patient may bring a grievance to the attention of anyone in the hospital or health care system, the hospital must educate employees at every level about the patient grievance process. Since CMS requires all grievances to be handled by the hospital’s designated grievance committee, a system must be in place to funnel the grievances to the grievance committee. Surveyors will review the hospital’s policies and procedures to determine whether personnel are encouraged to alert appropriate staff concerning any patient grievance.

13. Hospital collects and analyzes data obtained through the grievance process in order to improve quality.

The hospital must collect and analyze data obtained through the grievance process. CMS requires that the hospital close the quality assurance loop by collecting, analyzing and incorporating grievance and non-grievance information into the hospital’s Quality Assessment and Performance Improvement Program. The information channeled through the grievance process is only valuable to the extent that it can be captured and analyzed. Ideally, a hospital will utilize a uniform reporting system, thus enabling the hospital to capture statistically reliable information and track a patient’s grievance from start to finish. Surveyors will determine whether the hospital applies what it learns from the grievance process as part of its continuous quality improvement activities.

Compliance Snares

In order to have an effective patient grievance process, health care providers must avoid five compliance snares: decentralized grievance process; narrow interpretation of “grievance;” absence of documentation; failure to follow up with the patient; and limited compliance awareness.

Decentralized Grievance Process

CMS mandates that a hospital centralize the patient grievance process. This may be particularly challenging for a larger hospital system which may take a disjointed approach to processing patient grievances. Patient grievances may land in the any one of several departments such as Finance, Clinical Risk, Ombudsman, and Legal. Yet, regardless of where a patient grievance originates, it must be channeled to the designated grievance committee for investigation and follow up. A hospital which neglects to centralize the process may drop the ball and fail to investigate and follow up on patient grievances in a timely manner.

Narrow Interpretation of “Grievance”

In light of CMS’ broad definition of “grievance,” a hospital should err on the side of calling a complaint a grievance. The scope of the grievance definition is evident in the Interpretive Guidelines which state that if the patient requests a response from the hospital, the complaint is a grievance. Typically when a patient feels the issue is important enough to complain about, the patient expects a response. A hospital which narrowly defines “grievance,” may fail to respond in accordance with the CoP requirements, thus risking regulatory sanction. Additionally, a hospital which fails to correctly identify a patient grievance, may miss the opportunity to investigate and address critical systemic issues.

Absence of Documentation

CMS requires hospitals to document efforts to resolve the grievance and demonstrate compliance with CMS requirements. Surveyors will ask to see documentation indicating that patient grievances were investigated and resolved in accordance with the patient grievance CoP. Surveyors may also request evidence indicating that the hospital incorporates patient grievance information into its quality improvement process. A hospital which fails to document compliance with the patient grievance requirements, risks regulatory sanction.

Failure to Follow-Up with the Patient

CMS mandates that in its resolution of a grievance, the hospital provide the patient with a written notice which includes specific information. Additionally, sending a follow-up letter to a patient is good customer service. A hospital which does not follow-up in writing risks regulatory sanction and the consequences of having a dissatisfied patient.

Limited Compliance Awareness

It is essential that all personnel understand the patient grievance process, including correct identification of a patient grievance and the method by which patient grievances are investigated and resolved. Personnel should understand the inherent compliance risk of failing to appropriately respond to a patient grievance.

Service recovery efforts used to resolve patient grievances and non-grievances may have hidden compliance risks. For instance, the OIG has advised that Medicare or Medicaid providers must limit service recovery gifts to a retail value of no more than \$10 individually, and no more than \$50 in the aggregate per patient. The gift may not consist of cash or a cash equivalent. Additionally, service recovery efforts should not include waivers of copayments or deductibles. The OIG limits waivers of copayments or deductibles for patients with federal payer insurance. Such waivers must be non-routine, unadvertised, based on individualized determinations of financial need or exhaustion of reasonable collection efforts.^v There may be similar prohibitions set forth in contractual arrangements between the provider and private insurers.

A provider is well-advised to formalize service recovery efforts in policy and procedure. The grievance committee should work closely with the provider's compliance officer to stay current and responsive to compliance issues.

Conclusion

The patient grievance process is an essential element of an effective compliance program. Complying with CMS' patient grievance regulations and tailoring service recovery efforts to OIG mandates are no small tasks. An essential first step to ensuring compliance is to monitor the provider's current patient grievance process. The provider may then compare the current practice with the regulatory requirements and respond to any detected deficiency. Taking a proactive approach may lessen the risk of non-compliance.

ⁱ ASC patient grievance Condition for Coverage (CfC) is *located at* 42 CFR §416.50(a)(3).

ⁱⁱ ESRD Facility patient grievance CfC is *located at* 42 CFR 494.180(e).

ⁱⁱⁱ HHA CfC is *located at* 42 CFR §484.10(b).

^{iv} The Hospital patient grievance CoP is *located at* 42 CFR 482.13(a)(2).

^v OIG Special Advisory Bulletin Offering Gifts and Other Inducements to Beneficiaries” (August 2002) *available at* <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>