Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE EMERGENCY MEDICAL TREATMENT AND LABOR ACT

The Enforcement Process

JANUARY 2001
OEI-09-98-00221

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EXECUTIVE SUMMARY

PURPOSE

The purpose of this inspection was to evaluate the enforcement process for the Emergency Medical Treatment and Labor Act (EMTALA).

BACKGROUND

Congress passed EMTALA, part of the Consolidated Omnibus Reconciliation Act (COBRA) of 1985, in April 1986 to address the problem of "patient dumping." The term "patient dumping" refers to certain situations where hospitals fail to screen, treat, or appropriately transfer patients. According to Section 9121 of COBRA, Medicare-participating hospitals must provide a medical screening exam to any individual who comes to the emergency department and requests examination or treatment for a medical condition. If a hospital determines that an individual has a medical emergency, it must then stabilize the condition or provide for an appropriate transfer. The hospital is obligated to provide these services regardless of the individual's ability to pay and without delay to inquire about the individual's method of payment or insurance status.

Congress created a bifurcated enforcement mechanism for EMTALA within the Department of Health and Human Services. The Health Care Financing Administration (HCFA) authorizes investigations of dumping complaints by State survey agencies, determines if a violation occurred, and, if appropriate, terminates a hospital's provider agreement. The Office of Inspector General (OIG) assesses civil monetary penalties against hospitals and physicians and may exclude physicians from the Medicare program for repeated or gross and flagrant behavior. The HCFA *may* seek the input of the local peer review organization (PRO) after the State's investigation to help determine whether the hospital adequately screened, examined, and treated a patient but *must* seek PRO input in most circumstances before forwarding a case to the OIG if the alleged violation involves a question of medical judgment.

We interviewed staff at HCFA regional offices, State survey agencies, the PROs, and the OIG between June and December 1999. We also reviewed relevant HCFA manuals and guidelines as well as law journals. We obtained logs from HCFA that contain information about EMTALA complaints and the outcomes of investigations between Fiscal Years 1986 and 1998.

FINDINGS

The EMTALA enforcement process is compromised by long delays and inadequate feedback. Timely processing of EMTALA cases is a longstanding problem. Delays have worsened in recent years, despite a decline in dumping cases. In addition, HCFA regional offices often fail to communicate their decisions to State survey agencies and the PROs.

The number of EMTALA investigations and their ultimate disposition vary widely by HCFA region and year. Regional offices vary greatly in the number of EMTALA investigations that they conduct and the outcomes of those investigations. For example, one region found violations in 22 percent of its investigations while another region found violations in 68 percent of its investigations.

Poor tracking of EMTALA cases impedes oversight. The HCFA's investigation logs contain numerous errors and omit key information about dumping complaints and EMTALA investigations. Although HCFA's central office chose a particular software application for tracking EMTALA cases, some regional offices continue to use their own methods for data collection.

Peer review is not always obtained before HCFA considers terminating a hospital for medical reasons. The HCFA instructs States to obtain professional medical review during an EMTALA investigation, but this does not always occur. The HCFA has the option of requesting peer review, but this is discretionary even if the State did not obtain peer review. In most cases, the OIG must seek PRO input and may drop a case if the PRO finds that medical care was adequate.

RECOMMENDATIONS

We recommend that HCFA:

- **increase its oversight of regional offices,**
- **improve collection and access to EMTALA data,**
- **ensure that peer review occurs for cases involving medical judgment, and**
- **establish an EMTALA technical advisory group.**

AGENCY COMMENTS

We received written comments from HCFA on the draft report, which are included in the appendix. The HCFA concurred with our recommendations. The comments describe a dedicated HCFA effort to reduce backlogs, improve data collection, and increase coordination among the regions. The HCFA also offered several technical comments, which we have incorporated where appropriate.

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INTRODUCTION

PURPOSE

The purpose of this inspection was to evaluate the enforcement process for the Emergency Medical Treatment and Labor Act (EMTALA).

BACKGROUND

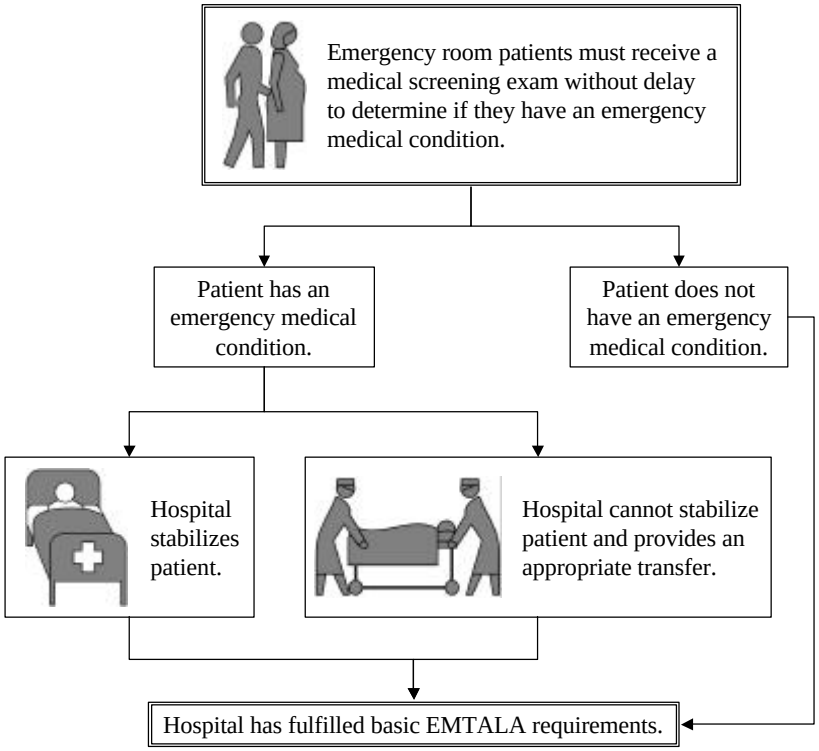
Requirements of the Emergency Medical Treatment and Labor Act

Congress passed EMTALA, part of the Consolidated Omnibus Reconciliation Act (COBRA) of 1985, in April 1986[1] to address the problem of "patient dumping." The term "patient dumping" refers to certain situations where hospitals fail to screen, treat, or appropriately transfer patients. According to Section 9121 of COBRA, Medicare-participating hospitals must provide a medical screening exam to any individual who comes to the emergency department and requests examination or treatment for a medical condition. If a hospital determines that an individual has an emergency medical condition,[2] it must then stabilize the condition or provide for an appropriate transfer. The hospital is obligated to provide these services regardless of the individual's ability to pay and without delay to inquire about the individual's method of payment or insurance status. Hospitals may transfer unstable patients only if a physician determines that the benefits of the transfer outweigh the risks or if requested by a patient who has been informed of both the hospital's EMTALA obligations and the risks of transfer. Hospitals with specialized care facilities, such as burn units, must, within their capacity, accept requests for appropriate transfers of patients who require such specialized care. The following diagram illustrates the basic EMTALA requirements:

[1]EMTALA became effective on August 1, 1986.

[2]Emergency medical condition is defined by law as "a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; (ii) serious impairment to bodily functions; or (iii) serious dysfunction of any bodily organ or part . . ."

Figure 1: Basic EMTALA Requirements

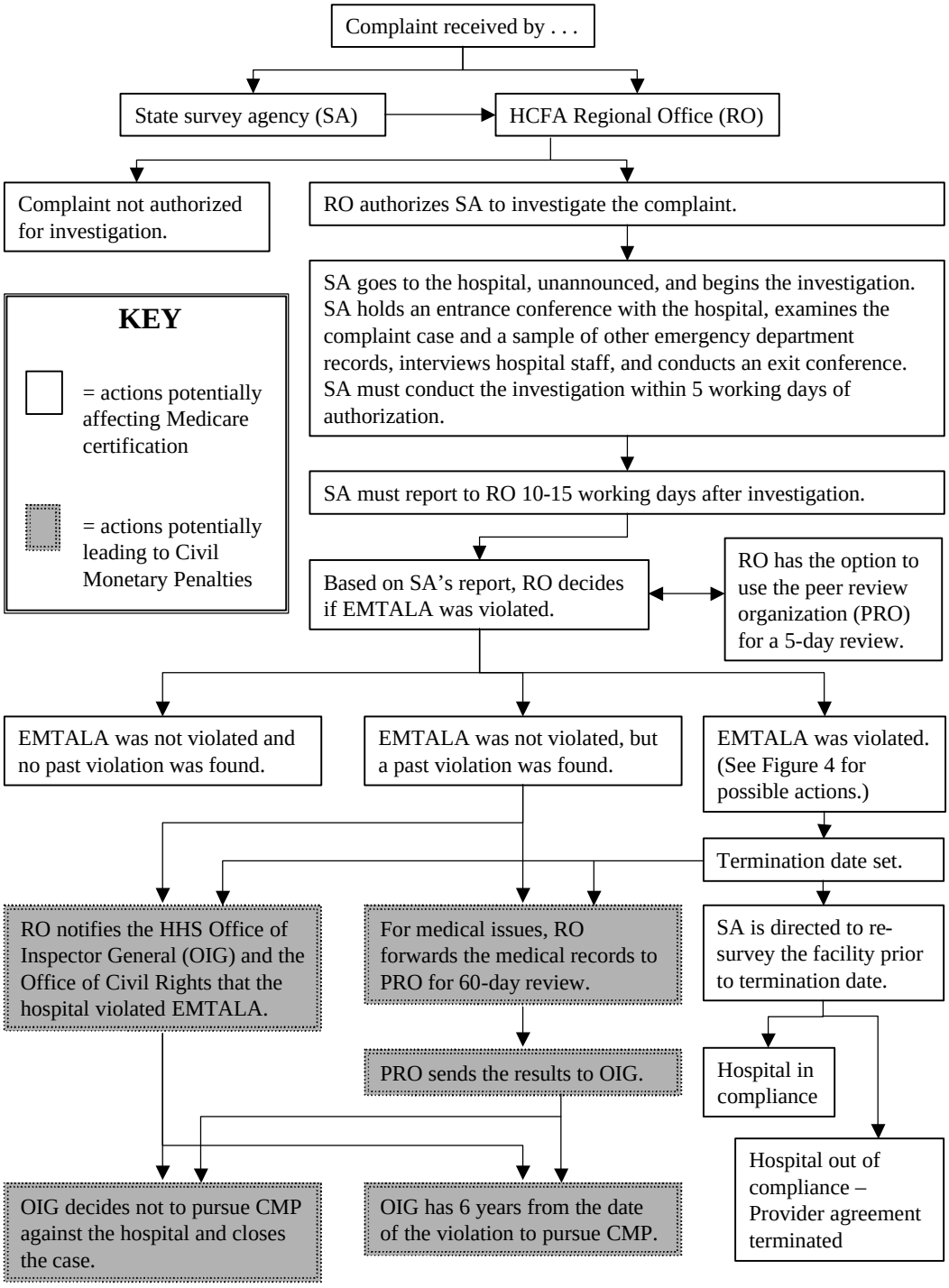


The specific requirements of EMTALA are incorporated in each hospital's Medicare provider agreement. The Health Care Financing Administration (HCFA) requires that in addition to providing a medical screening examination and necessary stabilizing treatment and appropriate transfers (i.e., the statutory requirements), hospitals must post signs, maintain a central log, an on-call roster and patient transfer records, and report EMTALA violations to HCFA or the State survey agency. All such obligations are considered equal, and failure to meet any of them constitutes a breach of the Medicare provider agreement and possible basis for termination. Hospitals also may be subject to civil monetary penalties of up to $50,000 per violation ($25,000 for hospitals with fewer than 100 beds) and civil action. Physicians who negligently violate EMTALA also are subject to civil monetary penalties and, for repeated or gross and flagrant violations, exclusion from Medicare.

Enforcement Mechanisms and Trends

The HCFA and the Office of Inspector General (OIG) are responsible for enforcing EMTALA (see Figure 2 for more information on the EMTALA enforcement process). The HCFA authorizes investigations of dumping complaints by State survey agencies, determines if a violation occurred, and, if appropriate, terminates a hospital's provider

Figure 2: EMTALA Enforcement Process



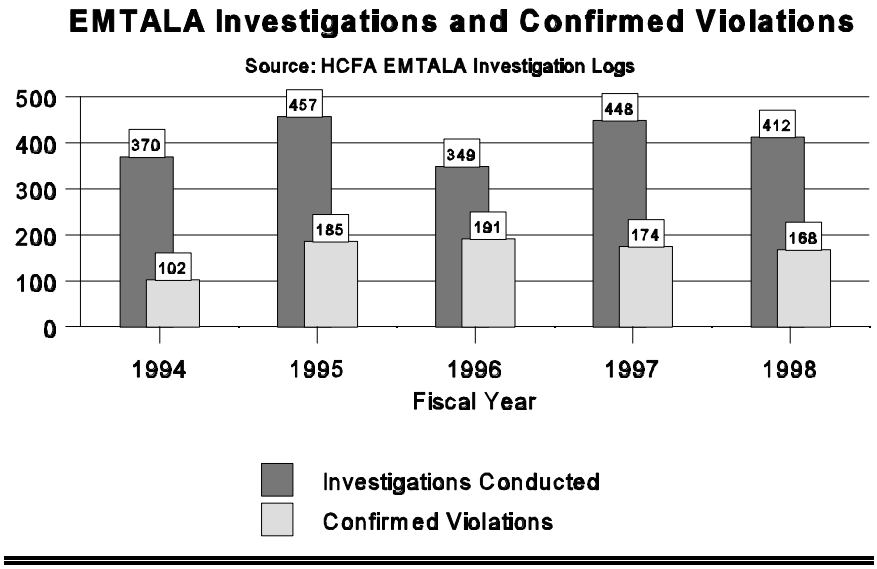
agreement. Within the OIG, the Office of Counsel to the Inspector General assesses civil monetary penalties against hospitals and physicians and may exclude physicians from the Medicare program. The HCFA may seek the input of the local peer review organization

(PRO) after the investigation, when HCFA must decide whether a violation occurred. However, by law HCFA must seek PRO input before it forwards a case to OIG which requires a medical judgement of a hospital's or physician's liability.[3]

State survey agencies perform unannounced, on-site investigations of hospitals and forward the results to the regional office. The purpose of these investigations is to determine whether a violation occurred, to assess whether the violation endangers patient health and safety, to identify any patterns of violations at the facility, and to assess whether the hospital has policies and procedures that implement EMTALA's provisions.

The number of EMTALA investigations, averaging 400 a year between Fiscal Years 1994 and 1998, is very small compared to the number of emergency department visits in the United States, which totaled approximately 97 million in 1999. In general, less than 50 percent of investigations confirm a dumping violation (see Figure 3).

Figure 3



Hospitals cited for dumping violations rarely lose their provider agreements. Since 1986, HCFA has terminated 13 hospitals from Medicare due to EMTALA violations. Only one of these terminations occurred after 1993, and it was voluntary. In practice, HCFA does not terminate a hospital's provider agreement if the hospital takes corrective action to prevent future violations.

Civil monetary penalties are relatively uncommon. The OIG closes more than half of the cases it reviews. To date, the OIG has processed 677 dumping cases; it has declined

[3]The OIG can impose a civil monetary penalty without PRO review "[i]f a delay would jeopardize the health or safety of individuals or when there was no screening examination. . ." 42 C.F.R. § 489.24 (g)(3)

353 cases and settled 226 (decisions in the remaining cases are pending). The number of civil monetary penalties assessed by OIG has increased dramatically in recent years, from a total of 79 settlements in Fiscal Years 1987 to 1997 to 61 settlements and judgments in 1999 alone. The increased activity reflects additional OIG staffing that resulted in the elimination of a backlog of cases rather than a surge in dumping complaints and confirmed violations (the statute of limitations for assessing civil monetary penalties is 6 years from the date of violation).

Recent Policy Developments

Implementation of EMTALA has evolved over the years due in part to a lengthy delay before final regulations were issued and growing concerns about the impact of managed care on access to emergency department services. In addition, issues continue to arise over the application of EMTALA to different hospital departments and operations.

In 1996, HCFA convened a work group composed of representatives of professional organizations and regulatory agencies to address enforcement issues as well as the definition of key terms in the law and the impact of managed care. The work group's objective "was to produce consensus recommendations for clarifications or changes to the statute, regulation, or HCFA's interpretive guidelines (enforcement procedures), with emphasis on changes that could be implemented quickly without legislative action or a formal rulemaking process."[4] The work group formed subgroups to address definitions, the enforcement process, and the relationship between EMTALA and managed care. The group submitted its recommendations in January 1997. The HCFA adopted some of these changes when it developed new guidelines for HCFA regional offices and State surveyors. These guidelines became effective in July 1998.

In 1998, HCFA also issued new instructions to State surveyors about the types of violations that warranted a 23-day rather than a 90-day termination process. Before 1998, HCFA treated almost all EMTALA violations as potential threats to patient health and safety that warranted a 23-day termination process. The new guidelines distinguished between violations that pose an immediate threat to patient health and safety that would trigger 23-day termination and those violations that do not affect health and safety and would justify a 90-day termination schedule (see Figure 4 on the following page). For example, violations involving a failure to complete required paperwork do not pose a threat to health and safety and therefore warrant a 90-day process.

In November 1999, HCFA and OIG published a Special Advisory Bulletin that recommended a number of "best practices" designed to help hospitals comply with EMTALA in a managed care environment where health plans may require hospitals to obtain prior authorization for emergency services. The Bulletin recommended that hospitals not seek such authorization but acknowledged that HCFA and OIG have no

[4]Joan M. Stieber and Linda J. Spar, "EMTALA in the '90s — Enforcement Challenges," *Health Matrix: Journal of Law-Medicine*, Volume 8, Number 1, Winter 1998, pp. 65-66.

authority to require health plans to pay for the screening and stabilizing treatment that hospitals are obligated to provide under EMTALA.

Figure 4: EMTALA Determination and HCFA Actions

Regional Office Determination	**Regional Office Action**	**Hospital Action**
Hospital is in compliance—No past violation	No action	No action
Hospital is in compliance—Past violation	Past violation is referred to OIG for consideration of possible civil monetary penalties	No action
Hospital is not in compliance—Violation does not pose an immediate and serious threat to patient health and safety	RO begins termination procedures and refers the case to OIG for consideration of possible civil monetary penalties	Hospital has 90 days to develop and implement a corrective action plan to cease termination procedures[5]
Hospital is not in compliance—Violation poses an immediate and serious threat to patient health and safety	RO begins termination procedures and refers the case to OIG for consideration of possible civil monetary penalties and to the Office for Civil Rights for possible action under Hill-Burton	Hospital has 23 days to develop and implement a corrective action plan to cease termination procedures[4]

Previous Office of Inspector General Studies on EMTALA

In 1988, shortly after Congress enacted EMTALA, the OIG issued two reports on the new law. The first report assessed whether hospital records provided enough information to determine the incidence of patient dumping. The study concluded that reviewing these records alone was inconclusive. The second report assessed the complaint and investigation process for dumping cases and found that the process was still evolving, coordination among different components needed improvement, and resolution of dumping complaints was time-consuming. In 1995, the Office of Inspector General issued a third report on enforcement of EMTALA and focused on HCFA. Although the report concluded that the investigation process was generally effective, it highlighted inconsistency among the regional offices with respect to their procedures and compliance with HCFA guidelines.

[5]If the hospital does not implement a corrective action plan within 21 days (in the case of a 23-day termination) or 75 days (in the case of a 90-day termination), the regional office notifies the public of the hospital's pending termination through "the most expeditious means available" (e.g., newspaper, television, or radio).

METHODOLOGY

We interviewed staff at four HCFA regional offices, eight State survey agencies, five PROs, and the OIG between June and December 1999. We visited HCFA regional offices in San Francisco, Dallas, New York, and Atlanta. We chose these regions because they have jurisdiction over half the nation's hospitals, and they have historically processed a large number of EMTALA cases.[6] We also reviewed some actual EMTALA cases. In each region, we visited two State survey agencies and interviewed surveyors and managers. We also interviewed staff from the PROs in the four HCFA regions. We used standardized discussion guides for all interviews.

In addition to interviews with Federal and State staff, we interviewed emergency department nurses and physicians as well as health care attorneys. We conducted a mail survey of emergency department staff and telephone interviews with more than 100 emergency department managers nationwide for a separate study on awareness and impact of EMTALA. During the telephone interviews, we asked managers about the impact of EMTALA and their experiences with EMTALA investigations. The companion report entitled *The Emergency Medical Treatment and Labor Act: A Survey of Emergency Department Staff (OEI-09-98-00220)*, discusses the results of our mail survey and interviews with emergency department staff.

We reviewed relevant HCFA manuals and guidelines as well as law journals. We also obtained logs from HCFA that contain information about EMTALA complaints and the outcomes of investigations between Fiscal Years 1986 and 1998.

[6]These four regions accounted for 65 percent of all EMTALA investigations between Fiscal Years 1994 and 1998 (1,330 out of 2,036).

FINDINGS

The EMTALA enforcement process is compromised by long delays and inadequate feedback

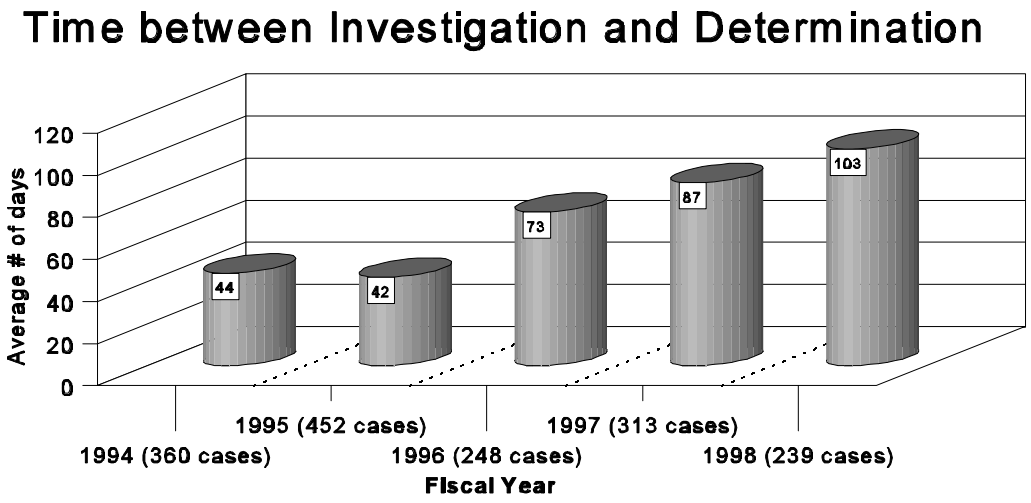
The HCFA requires State survey agencies to complete investigations within 5 working days of authorization and submit their reports 10 to 15 working days after the investigation is complete. These investigations are labor-intensive and require surveyors to review a large volume of documents, including a log of emergency department cases for the past 6 to 12 months, policy manuals, minutes from medical staff meetings for the past 6 to 12 months, credential files, and quality assurance minutes. In addition, State staff must review 20 to 50 medical records for emergency department patients. We found that State agencies generally meet the mandatory time frames.

Long delays. Although strict time frames apply to State survey agencies that investigate complaints of patient dumping, HCFA itself is not subject to any. Hospitals may wait a long time to find out the outcome of an investigation and could be subject to a fast-track termination for an incident that occurred months or years before. Long delays in reviewing and deciding cases defeat the purpose of the 23-day termination process, which is to address immediate threats to patient health and safety.

The logs that we obtained from HCFA central office confirm that timely processing of cases is a longstanding problem (see Figure 5). Between 1994 and 1998, the period reflected in the logs, regional offices took an average of 65 days after the State's investigation to determine if a violation occurred. Seven of the 10 HCFA regional offices sometimes took as long as a year or more to decide whether a hospital violated EMTALA. Many cases in the logs were marked as "pending," despite the fact that the original complaint often was received years before. For example, the 1998 logs show 20 cases dating from 1996 as "decision pending."

Three State survey agencies that we visited expressed concern about long processing times in HCFA regional offices. Staff in one State told us that in some cases 2 years or more elapse before the hospital finds out its status. We heard similar concerns from emergency department administrators. Three administrators whom we interviewed told us that their hospitals had been investigated a year or more earlier, but they were still unsure of the outcomes. In one case, the hospital was not cited until 4 years after the investigation had occurred. "[The investigation] loses punch if it takes too long," said one emergency department director, "[because] the staff in question leave." Staff in HCFA regional offices acknowledged that they have a backlog of cases.

Figure 5



Inadequate feedback. State survey agencies, PROs, and hospitals repeatedly complained about lack of feedback from HCFA about the outcome of EMTALA cases. State agencies and the PROs, which review material related to alleged dumping violations, rarely learn the outcome of the cases they review. The survey agencies are particularly interested in the outcome, because they also license hospitals for the State.

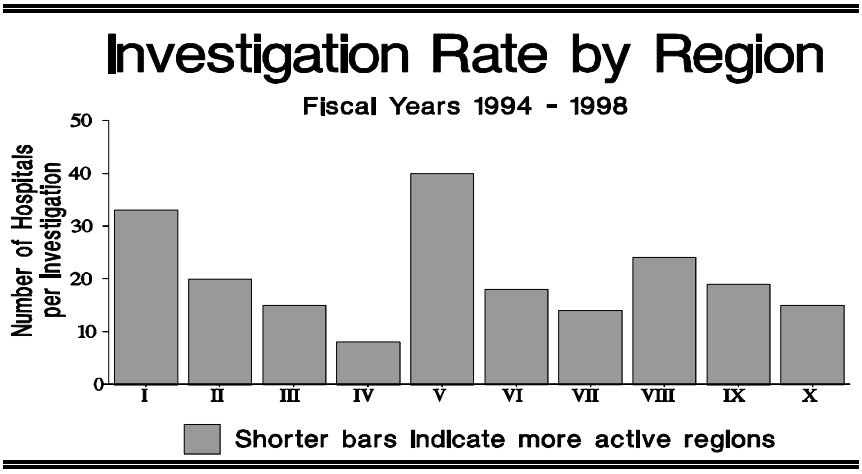
The number of EMTALA investigations and their ultimate disposition vary widely by HCFA region and year

The volume of investigations within regions occasionally shifts sharply by year, and we identified no reason for these swings. In 1994, for example, one of the largest HCFA regions handled 119 EMTALA cases, the second highest total nationally. The workload has since dropped precipitously, and in 1998 the same region handled only three EMTALA cases. Another region logged 42 cases in 1996 and only 7 in 1998. Conversely, 7 of the 10 regional offices have seen a rise in their EMTALA caseloads since 1994. One region's caseload climbed from 18 cases in 1994 to 74 cases in 1998. Another region's caseload jumped from 13 cases in 1994 to 48 in 1998.

This inconsistency may mean that hospitals have a higher or lower chance of being investigated, depending in large part on their location (see Figure 6). Nationally, we identified 1 investigation for every 15 hospitals between Fiscal Years 1994 and 1998. In one region, however, there was one EMTALA investigation for every eight hospitals in the region during the same period. At the other extreme, the average was 1 investigation for every 40 hospitals in another region. These variations may, in part, be explained by staffing differences, regional priorities, or the fact that some regional offices are more

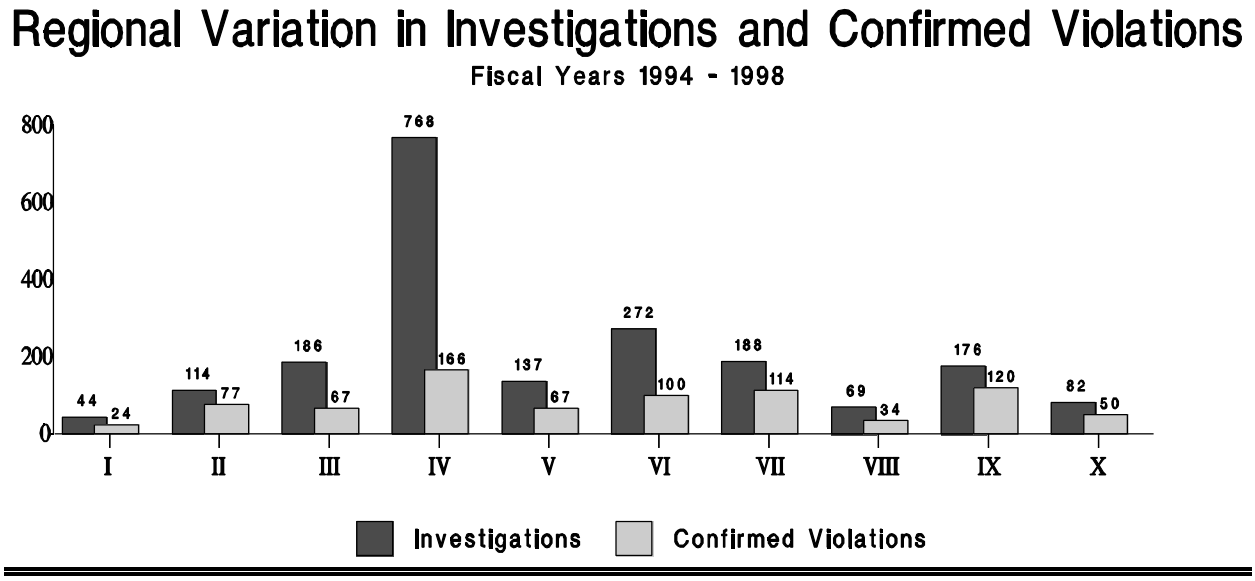
aggressive about screening complaints before they authorize State survey agencies to conduct investigations.

Figure 6



The percentage of investigations that confirm a dumping violation varies greatly by region (see Figure 7). Nationally, 40 percent of investigations substantiated a violation between Fiscal Years 1994 and 1998. One region, however, found violations in 22 percent of its investigations while another region found violations in 68 percent of its investigations.

Figure 7



In 1997, the Enforcement Process and Procedures Subgroup of the EMTALA Work Group noted "that there was substantial inconsistencies from state agency to state agency and from region to region, in both understanding of the guidelines and in the application of the guidelines and law at the respective levels." To address these inconsistencies, the subgroup recommended that HCFA consolidate all rules, regulations, and guidelines for State survey agencies and HCFA regional offices in a single manual.

Poor tracking of EMTALA cases impedes oversight

Data collection for EMTALA cases has historically been inconsistent and incomplete. We requested investigation logs from HCFA central office in November 1998 and received an incomplete set in June 1999. The documents contained numerous errors and omissions; each page was stamped "draft," even though the logs reflected activity between 1994 and 1998. Key information was absent. Details were missing concerning the complaints that did not result in an investigation, the dates investigations were authorized, and the nature of the violations, which can range from technical violations involving a failure to complete necessary paperwork to more serious infractions such as failure to perform a medical screening exam. Common errors in the 1998 logs include illogical dates (e.g., dates of investigation precede dates of complaint) and incorrect provider numbers.

Inconsistencies in data collection formats between regions and central office may explain the serious and ongoing problems with the logs. The HCFA central office decided to track EMTALA cases in 1995 and requires regions to submit monthly logs, but regional offices continue to use their own methods for data collection. One region uses a different software application to track cases and previously tracked cases manually (staff reported that they have lost EMTALA files). Another region developed its own spreadsheet, and staff there told us that they had received no guidance from central office about tracking cases. At the time of our interview with this region in June 1999, staff had not submitted logs for Fiscal Year 1998. Another region maintains both electronic and manual logs.

The historical absence of an accurate, complete central database limits HCFA's ability to oversee regional offices. Specifically, central office cannot track regional workloads and address longstanding problems. Such problems include lengthy delays before regional offices determine whether violations occurred, unacceptable backlogs of cases that are several years old, and insufficient screening of complaints to assess their legitimacy.

Peer review is not always obtained before HCFA considers terminating a hospital for medical reasons

Although HCFA instructs State survey agencies to conduct professional medical review (physician review) during their investigations of alleged dumping violations and provides explicit guidelines about what this review should entail, this does not always occur. In 1998, HCFA specified that "review physicians should be board-certified (if the physician being reviewed is board-certified) and should be actively practicing in the same medical specialty as the physician treating the patient whose case led to an alleged violation." Three State survey agencies out of the eight that we contacted had problems obtaining appropriate physician review. One agency does not employ or contract with any physicians, and the remaining two had longstanding problems finding physicians to work for the State.

After the State's investigation, regional offices may ask their local PRO to perform a 5-day review to obtain additional medical expertise. This review is discretionary, even if the State did not obtain professional medical review during its investigation. Four out of the five PROs that we contacted either conduct few or no 5-day reviews.

In contrast, PRO review is, in nearly all circumstances, mandatory before OIG assesses civil monetary penalties, and in many instances the PRO's assessment leads OIG to drop a case. In 1990, Congress added a provision to section 1867 of the Social Security Act that requires PRO review under certain circumstances before imposition of civil monetary penalties. By statute, the PRO has 60 days to complete this review. The PRO assesses whether a patient had an emergency medical condition that was not stabilized, in addition to other medical issues. According to HCFA guidelines, "the PRO must offer to discuss the case with the involved physician(s) and hospital(s) and provide them with an opportunity to submit additional information." In 1997, the OIG noted that in some regions the PROs disputed HCFA's decision about a case as much as 33 percent of the time.[7]

[7]Recommendations, The Enforcement Process and Procedures Subgroup, p. 4.

RECOMMENDATIONS

The HCFA central office should increase its oversight of regional offices

The EMTALA enforcement process is marked by considerable inconsistency; this is the result of the decentralized nature of the process and the sheer number of agencies involved.

We recommend that HCFA central office:

- monitor regions' conduct of investigations more closely;
- consolidate all rules, regulations, and guidelines in a single manual; and
- establish time frames for regional decisions and intervene if regional offices fail to meet them.

The HCFA should continue to improve collection and access to EMTALA data

To facilitate oversight of the regional offices and State survey agencies that play critical roles in EMTALA enforcement, HCFA central office should continue to improve data collection. Without aggregate data on complaints and the nature of dumping violations, it is impossible to assess the prevalence of patient dumping or whether the violations threaten patient health and safety. Also, PROs and State survey agencies should have access to data on EMTALA cases so that they can learn the outcomes.

The HCFA should ensure that peer review occurs before initiating termination actions in cases involving medical judgment

The HCFA expects States to obtain professional medical review when they investigate hospitals but does not seek peer review if State agencies fail to follow HCFA's instructions. As a result, hospitals may be subject to termination without the benefit of peer review of a physician's actions. The HCFA should ensure that peer review occurs before it seeks termination of a hospital's provider agreement on medical grounds. According to HCFA guidelines, "appropriate physician review may be performed by qualified SA [State agency] physicians or under agreements or contracts with the State PRO, the State or local medical association, or other physician groups or individuals."

The HCFA should establish an EMTALA technical advisory group

The HCFA disbanded the EMTALA Work Group after it submitted its recommendations in January 1997. Questions about EMTALA continue to arise, however, and the health care landscape continues to change. Given the enormous complexity and impact of EMTALA on hospitals and physicians, HCFA should consider establishing a technical advisory group comprised of representatives from organizations such as the American College of Emergency Physicians, American Hospital Association, and the American Association of Health Plans as well as State surveyors, patient advocacy groups, and staff from the PROs. Like the original Work Group, the new group could help the agency resolve any emerging issues related to implementation of the law. Current issues include specialists who refuse to serve on call panels and inconsistencies between State and Federal law governing emergency medical services.

AGENCY COMMENTS

We received written comments from HCFA on the draft report, which are included in the appendix. The HCFA concurred with our recommendations. The comments describe a dedicated HCFA effort to reduce backlogs, improve data collection, and increase coordination among the regions. The HCFA also offered several technical comments, which we have incorporated where appropriate.

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

DATE: JAN 16 2001

TO: June Gibbs Brown
Inspector General

FROM: Robert A. Berenson, M.D.
Acting Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Reports: "The Emergency Treatment and Labor Act: Survey of Hospital Emergency Departments," (OEI-09-98-00220) and "The Emergency Treatment and Labor Act: The Enforcement Process," (OEI-09-98-00221)

Thank you for the opportunity to comment on the above draft reports. The Health Care Financing Administration (HCFA) is absolutely committed to vigorously implementing the Emergency Medical Treatment and Labor Act (EMTALA). Our efforts are two-pronged: by providing clear guidance to hospitals about EMTALA requirements through effective outreach and education we try to prevent violations, while taking fair and timely action when EMTALA violations occur.

Enacted in 1986 in response to concerns that patients were being denied emergency care for financial reasons, EMTALA has played a critical role in ensuring that individuals with emergency medical conditions receive a medical screening and stabilization, or an appropriate transfer to another facility. Between 1986 and 1994, the number of complaints of EMTALA violations rose steadily from 3 (of which 2 were confirmed) to 1,851 (465 confirmed). In 1994, we published an interim final rule, clarifying the obligations of hospitals under EMTALA. Since then, the number of complaints has hovered between 300 and 500, with confirmed violations ranging between 180 and 210 per year.

While no violation is acceptable, we think the dramatic decline in number of complaints is a testimony to EMTALA's success in ensuring patient access to emergency care. At the same time, we are taking a number of steps to bolster our EMTALA efforts.

Between fiscal years 1996 and 2000, we received over 2,000 EMTALA complaints across the country. Of those, more than one-third were attributable to one HCFA region, which, as a result, developed a backlog of unresolved cases. We have been addressing this problem by increasing the number of staff devoted to processing backlogs and redistributing a portion of the complaints to other ROs for reviews. In the past 6 weeks, for example, we have processed 127 cases in this region, reducing the backlog by 29 percent. Based on this experience, we expect to eliminate the backlog of complaints within 4 to 6 months.

Page 2- June Gibbs Brown

Similarly, we have found a disproportionate number of complaints in one state. We are working in that state, through focused intervention such as outreach and training to hospitals, to avert future EMTALA violations.

For the longer term, we are stepping up communication and coordination of our prevention and enforcement activities. We are revising our State Operations Manual and our Interpretative Guidelines to provide clearer guidance to our Regional Offices and the State Agencies on investigating EMTALA complaints. We are also developing standardized forms and procedures for handling EMTALA complaints, and maintaining regular contact via conference call with our regions, so we can intervene more promptly when problems arise.

We also plan to issue a Notice of Proposed Rulemaking in the near future that will further clarify EMTALA requirements as they apply to a changing healthcare delivery system.

It is in this context that we view the OIG reports. We welcome the OIG's recommendations and look forward to working together to ensure that the statute is effectively and appropriately enforced.

We find the observations in the first report, *Survey of Hospital Emergency Departments*, to be largely consistent with our own assessments of EMTALA compliance issues based on our own interviews with hospital emergency departments. We agree with the conclusions of this report, and have submitted only the attached technical comments.

We also agree with the conclusions of the second report, *The Enforcement Process*, regarding needed changes in how HCFA responds to complaints of EMTALA violations. We are pleased to report that we have already made significant inroads in strengthening our processes for complaint investigation and resolution. We have reduced complaint backlogs, developed resource redeployment strategies to address the geographic variation in complaints received, and improved data reporting.

We appreciate the opportunity to comment on the issues raised. Detailed information on concrete steps we have taken or planned are contained in our responses to each recommendation below.

OIG Recommendation
The HCFA central office (CO) should increase its oversight of ROs.

HCFA Response
HCFA concurs that there should be greater communication and coordination between the CO and the regions, and has already taken steps to achieve this. For example, in May 1999, CO staff implemented an improved log reporting process to assist RO staff in reporting complaints to CO and changed the reporting cycle from quarterly to monthly. In addition, monthly conference

calls have been initiated to discuss EMTALA issues and clarify policies to promote consistent EMTALA enforcement across the regions.

Currently the State Operations Manual (SOM), rules, regulations, and interpretative guidelines are located on the HCFA website. The Center for Medicaid and State Operations is in the process of redesigning the website to establish clear and precise links to these documents. In addition, HCFA will review and examine the SOM policies and procedures concerning EMTALA enforcement and make revisions as appropriate.

In April 2000, a HCFA work group convened in Baltimore to begin revising the Interpretative Guidelines-Responsibilities of Medicare Participating Hospitals in Emergency Cases (Appendix V). The goal of this revision is to clarify national policies and to include in the SOM timeframes for HCFA to review State agencies' investigative findings. HCFA will monitor the status of these investigations and review activities and work closely with its regions to ensure that complaints are promptly and appropriately resolved.

OIG Recommendation
The HCFA should continue to improve collection and access to EMTALA data.

HCFA Response
EMTALA is a complaint-driven process requiring precise documentation to evaluate enforcement activity and assess the complaint investigation process. In 1999, HCFA took numerous steps to improve the timeliness and accuracy of reports of EMTALA allegations and investigations. Specifically, HCFA is now compiling reports monthly, rather than quarterly. The agency has also developed log instructions and a standardized log format to promote consistency of reporting among the regions. Although some advances in reporting have been made, HCFA will continue to work to identify other mechanisms to improve the reporting of EMTALA complaints.

We also expect that enhancements in a new survey and certification data system (Quality Improvement and Evaluation System or QIES) will address EMTALA enforcement issues, including more timely access and public disclosure of EMTALA findings.

OIG Recommendation
The HCFA should ensure that peer review occurs before initiating termination actions in cases involving medical judgment.

HCFA Response
HCFA generally agrees that prior to initiating termination actions in cases involving medical judgment, peer review of a physician's action should be performed by a physician (State agency consultant or Peer Review Organization (PRO)). HCFA is currently reviewing its hospital complaint investigation procedures, including handling of EMTALA complaints and will revise these policies as needed.

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The group reviewing these procedures is also coordinating its efforts with HCFA's Office of Clinical Standards and Quality, which is reexamining the PROs role in responding to complaints.

OIG Recommendation
The HCFA should establish an EMTALA technical advisory group.

HCFA Response
In 1996-1997, HCFA met with a group of interested stakeholders from professional organizations and consumer advocate groups. The group discussed possible clarifications or changes to the statute, regulation, and interpretative guidelines for EMTALA, and HCFA has developed and implemented some of the recommendations raised by the various stakeholders.

HCFA agrees that continued consultation with stakeholders is necessary and that a more formal approach may be effective. We will work closely with the OIG and the Office of the General Counsel to determine the best strategy to ensure meaningful consultation.

Attachment