
PATIENT DUMPING AFTER COBRA

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
RESPONSE TO COMPLAINTS**



OFFICE OF INSPECTOR GENERAL
OFFICE OF ANALYSIS AND INSPECTIONS

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EXECUTIVE SUMMARY

PURPOSE

The purpose of this inspection was to (1) assess the procedures in place at the Health Care Financing Administration (HCFA), the Office for Civil Rights (OCR), and the Office of Inspector General (OIG) for the investigation of and response to complaints of patient dumping received by the Department; (2) determine what problems have been encountered in the investigation and response to complaints; and (3) identify what steps can be taken to correct any difficulties.

BACKGROUND

This is the second of two reports issued by the Office of Inspector General (OIG) concerning the issue of patient dumping. The first report on this subject, "Patient Dumping After COBRA: Assessing the Incidence and the Perspectives of Health Care Professionals," was released in August 1988. It attempted to determine if the rate of patient dumping could be measured and if health care professionals saw problems in the current process of identifying and reporting alleged cases. During that inspection, 25 compliance reviews of hospitals were conducted along with interviews with 88 health care professionals across the country.

This inspection assessed internal procedures for handling complaints of patient dumping. The HHS has jurisdiction concerning patient dumping under two different statutory authorities, the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985, and the Hill-Burton Act of 1946. The HCFA and OIG are responsible for enforcing the COBRA provisions, while OCR is responsible for Hill-Burton enforcement in this area.

To date considerable criticism has been levied at the Department for lack of vigor in enforcing its anti-dumping authorities. All three components have come under fire for a lack of aggressiveness in pursuing and taking action on alleged cases. Critics point to the small number of cases in which penalties have been levied or action has been taken by HCFA, OIG or OCR as evidence of a lack of commitment by the Department in this area.

METHODOLOGY

Interviews were held with representatives of HCFA, OCR and OIG in Washington, D.C.; Baltimore, Maryland; Atlanta, Georgia; Dallas, Texas; and San Francisco, California to discuss current practices and initiatives in anti-dumping enforcement. In addition, OIG regional personnel reviewed case files in Atlanta, Dallas, and San Francisco to determine time frames for referral and investigation, as well as document conclusions reached and actions taken.

FINDINGS

- Procedures for the investigation and referral of dumping complaints are relatively new or still evolving. The OCR issued specific instructions to its regional offices in April 1988. While HCFA and OIG issued interim instructions in mid-1987, HCFA has drafted new implementing instructions for the Regional Office Manual and State Operations Manual and OIG is in the process of preparing a section for investigating dumping complaints for the Special Agent Handbook.
- Coordination between the components has not been a priority in the past. Steps are being taken to improve this situation, including meetings at all levels between the components. However, such coordination alone may not suffice to avoid situations in which the components are taking independent actions in the course of their separate investigations.
- The number of complaints received by the Department has increased over time, from a total of 4 complaints received between October and December 1986 to 33 complaints in the same time period a year later.
- Most complaints investigated by the components to date in the three regions studied have been determined to be unsubstantiated. When complaints are substantiated, the most extreme penalties available (termination, suspension, imposition of civil money penalties (CMPs), or referral to Department of Justice) are rarely used.
- Many cases substantiated by HCFA are still under investigation by OIG. Most cases referred to OCR by HCFA were deemed by OCR as falling outside Hill-Burton.
- Resolution of dumping complaints is time consuming. In the three regions studied, it has taken an average of 30 days for HCFA to refer the complaint and receive results from the State agency; anywhere from the same day to 214 days for HCFA to make a formal referral to the OIG; and anywhere from 42 to 241 days for OIG to complete its investigation and refer the case for settlement. In the two cases where CMP settlement occurred, it took 177 and 214 days to reach agreement.

RECOMMENDATIONS

- *The HHS should align responsibilities of its component agencies in order to assure a unified response to a single complaint, or series of complaints involving a single hospital. The undertaking of three separate investigations--one by OCR, one by HCFA, and one by OIG--results in duplicative efforts, inefficient expenditure of resources, inconsistent responses, and a lengthened response time.*

- *The HCFA and OCR should propose legislation to better align their authorities under COBRA and Hill-Burton and to establish a common departmental definition as to what constitutes patient dumping under the relevant provisions of those statutes.*
- *A set of guidelines should be developed to outline actions that can be taken in response to varying levels of violations. We also recommend the use of a set of time frames for investigation and resolution of complaints, and the use of a screening mechanism (such as the State agency) to direct resources to more productive cases.*

AGENCY COMMENTS

We solicited and received comments to the draft report from HCFA and OCR. The HCFA is in agreement with all the report recommendations. However, OCR had a number of comments regarding the inspection findings and was not fully supportive of the report's recommendations. The OCR questioned the characterization of some of the findings, and sought to provide additional information on OCR efforts in the area of patient dumping. Where appropriate, certain statements made in the report were clarified on the basis of these comments.

Comments to the draft report are included in appendix D.

INTRODUCTION

BACKGROUND

This is the second of two reports issued by the Office of Inspector General (OIG) concerning the issue of patient dumping. Patient dumping can be defined as the refusal of a hospital to provide necessary treatment to an emergent patient or woman in active labor on a basis (primarily the inability to pay for services) unrelated to the hospital's capability to provide care or the patient's need for care. The first inspection on this subject¹ attempted to determine if the rate of patient dumping could be measured and if health care professionals saw problems in the current process of identifying and reporting alleged cases. The report was released in August 1988 and reported that (1) objective measurement of the problem was difficult due to current record keeping practices by hospitals; (2) hospitals did not uniformly or consistently report incidents of dumping to the proper authorities; and (3) perceptions varied widely among practitioners concerning the rate of dumping at their facilities.

In light of these findings, the OIG recommended that steps be taken to encourage hospitals to report suspected cases of dumping, including making reporting of suspected cases of dumping a condition of participation in the Medicare program, posting notices in hospital emergency rooms (ERs), clarifying definitions, and conducting direct outreach to professional associations such as the American College of Emergency Physicians (ACEP). The OIG also recommended that anti-dumping regulations require that all ER records clearly identify transferred patients, in order to support compliance reviews conducted by the Department of Health and Human Services (HHS).

This inspection attempted to determine how HHS components responsible for the enforcement of anti-dumping laws have responded in the past, and would respond in the future, to complaints of patient dumping received by the Department. The HHS has jurisdiction concerning patient dumping under two different statutory authorities, with three components within HHS involved in enforcement activities: the Office for Civil Rights (OCR), the Health Care Financing Administration (HCFA), and the OIG.

The first authority under which the Department has jurisdiction over patient dumping is the community services assurances provision of the Hill-Burton Act of 1946, 42 U.S.C. 216, 300m-4 and 300o-1(6) (titles VI and XVI), and the accompanying regulations (42 CFR section 124.603(b)) issued in 1979. (Appendix A contains the Hill-Burton regulation.) The Hill-Burton Act, which provided construction and modernization grants to hospitals, required grantees to make certain assurances: among them, that they would make their facilities available to persons residing in their community. The regulation issued in 1979 requires emergency medical services to be provided regardless of a patient's ability to pay for such services and prohibits the transfer or discharge of patients unless appropriate medical personnel determine that such action will not risk substantial deterioration of the patient's condition. The OCR has jurisdiction over the Hill-Burton authorities.

The Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 amended title XVIII of the Social Security Act. Draft implementing regulations were issued in June 1988 (see appendix B). This authority, effective August 1986 and under the jurisdiction of HCFA and OIG, is much more specific than the broad statutory authority of Hill-Burton. The COBRA requires that (1) hospitals screen all patients presenting themselves for treatment to determine if an emergency condition is present or the patient is in active labor; (2) hospitals stabilize patients before transfer, unless the patient has requested the transfer or a certification has been signed by a physician attesting that the benefits of the transfer outweigh the risks; (3) the transferring hospital contact the receiving facility for permission to transfer; (4) medical records accompany the patient; and (5) the hospital effectuate the transfer through qualified personnel and equipment.

There is certain jurisdictional overlap, but also certain distinction, between these two authorities. For example, the Hill-Burton provision applies only to facilities which received Hill-Burton funds. The COBRA applies to all facilities which are Medicare-participating. Consequently, not all complaints actionable under COBRA would be actionable under Hill-Burton, since not all Medicare-participating hospitals received Hill-Burton funds. However, all Hill-Burton complaints *are* actionable under COBRA, since all Hill-Burton facilities are required to be Medicare-participating.

On the other hand, because COBRA is more specific, a violation under COBRA might not be a violation under Hill-Burton. Failure to provide a physician certification, contact the receiving facility or provide adequate transportation, for example, are violations of COBRA only.

Remedies under the two authorities vary greatly, as well. Under Hill-Burton, OCR may only negotiate a compliance plan or sue for specific compliance through the Department of Justice (DOJ). Under COBRA, however, a hospital or responsible physician may be suspended or terminated from the Medicare program, and assessed a civil money penalty (CMP) of up to \$50,000 per violation (as amended by the Omnibus Budget Reconciliation Act of 1987). While HCFA is responsible for pursuing termination actions, the Secretary of HHS delegated to OIG the responsibility for suspensions and assessment of CMPs, resulting in shared enforcement authority within the Department.

As a result of these separate authorities, differing conclusions can be reached by OCR and HCFA in determining whether a hospital has engaged in patient dumping. Actions taken will always differ, based on their different enforcement authorities. While HCFA and OIG should always reach the same conclusion, since both are relying on the same statutory base, these components may also disagree on the appropriate action to take. As discussed in the findings, the involvement of three components under two separate legislative authorities has sometimes resulted in confused and duplicative actions by the Department concerning a single hospital.

To date considerable criticism has been levied at the Department for lack of vigor in enforcing its anti-dumping authorities. All three components have come under fire for a lack of aggressiveness in pursuing and taking action on alleged cases. A former Director of OCR, Sylvia Drew Ivie, testified before the Human Resources and Intergovernmental Relations Subcommit-

tee of the House Committee on Government Operations in August 1986 that dumping occurs regularly at Hill-Burton facilities and OCR's actions in enforcing the community service obligation have been minimal.² A report issued by the same subcommittee in March 1988 based on hearings in fall 1987 criticized both HCFA and OIG for failing to use their enforcement powers under COBRA. Judith Waxman of the National Health Law Project testified that "lawyers are hesitant to use [the COBRA] process because they have one of two experiences; either they never hear a response at all from the agency, or the response is so delayed that their clients are totally discouraged by the wait and the meagerness of the ultimate results."³ The HHS has been further criticized for the delay in publishing regulations supporting the anti-dumping provisions of COBRA, which were eventually released in draft in June 1988. Critics point to the small number of cases in which penalties have been levied or action has been taken by OCR, HCFA, or OIG as evidence of a lack of commitment by the Department in the area.

PURPOSE

The purpose of the inspection was to determine how the various components investigate and respond to complaints of patient dumping, what problems had been encountered, and what corrections are needed to correct any past difficulties. The overall objectives of the study were to assess:

- if procedures are in place for the timely investigation and resolution of complaints;
- if procedures exist for the referral of complaints to all HHS components with jurisdiction; and
- what the components' actual experiences have been in regard to receipt of and response to complaints of patient dumping.

METHODOLOGY

In order to support these objectives, personnel from the Office of Analysis and Inspections (OAI) of the OIG conducted on-site interviews with HCFA, OCR, and the Office of Investigations (OI) OIG headquarters personnel in Washington, D.C. and Baltimore, Maryland. A pre-inspection visit with representatives of the three components in the Philadelphia, Pennsylvania regional office was undertaken to focus inspection issues and provide background understanding.

Interviews were also conducted with regional personnel from all components in Atlanta, Georgia; Dallas, Texas; and San Francisco, California. These three regions received over 90 percent of all dumping complaints received by the Department as of April 1988 and were therefore considered to have the most substantial experience in investigating patient dumping allegations. We did not attempt to determine why complaints received by HHS are

concentrated in these three regions, although the existence of strong State laws in Texas and California may be one explanation for increased reporting of cases in those areas.

In addition to interviews with regional personnel, case files maintained by the three components in those regions were reviewed to determine time frames for referral and investigation,⁴ as well as to document conclusions reached and actions taken. No attempt was made to assess the *quality* of the investigations undertaken by any of the components.

FINDINGS

Procedures for the investigation and referral of dumping complaints are relatively new or are still evolving.

Several persons interviewed at the regional level indicated that, in the past, they had conducted investigations of complaints of patient dumping "by the seat of our pants." For over a year after enactment of COBRA, no specific instructions were issued to the regional offices (ROs) concerning the proper procedures to follow in the event a complaint of patient dumping was received. Up until this time, the available guidance from headquarters for HCFA, OIG, and OCR personnel was limited to investigative and compliance standards to deal with all complaints, not just those involving patient dumping, and no guidance had been given in regard to the referral of complaints to other components with jurisdiction. In the past year, initiatives have been taken by all three components to provide more specific guidance to their ROs in these areas.

HCFA Instructions

The HCFA provided interim instructions to its ROs in June 1987 with additional instructions released later in June and in July of that year. Under these instructions the State agency must conduct an investigation of the complaint within 5 days surveying, at minimum, emergency services and medical staff under the conditions of participation. A "fast track" termination is to be initiated if results indicate that the hospital is out of compliance. According to the July instruction, OCR is also to be notified of all complaints.

The HCFA now has in draft new implementing instructions for the Regional Office Manual and State Operations Manual concerning dumping complaints. The instructions, in addition to setting timeframes for investigation by the State agency, also set timeframes for peer review organization (PRO) action: where the PRO is involved for medical review, the instructions stipulate that the PRO must provide written evaluations within 5 working days of all cases referred for investigation.⁵

The HCFA has advised its ROs that conditions of participation for emergency services and medical staff must be surveyed in validation surveys and that findings of noncompliance from those surveys should also be used to initiate a "fast track" termination. In one region, a letter was sent to the PROs stating in part: "In the course of a routine review, the PRO may identify that a hospital admission followed a transfer from another hospital emergency service. If the evidence in the admitting hospital's record indicates that the patient was inadequately treated in an emergency room or that arrangements had not been made for an appropriate transfer...the PRO should notify this office." A referral sheet to be completed by the PRO in such cases was attached.

The latest instructions to be inserted in the State Operations Manual also provide more detail on investigating complaints and include a worksheet for gathering pertinent infor-

mation. Information to be gathered by the surveyor at the facility which allegedly dumped the patient includes (1) verification that emergency services are available; (2) verification by review of a sample of emergency patient and active labor patient records that these patients were appropriately screened (including the complaint that prompted the investigation); (3) verification of whether emergency care was rendered that stabilized the condition; and (4) verification that patient transfers complied with COBRA requirements.

OIG Instructions

The OIG issued interim instructions in July 1987 to its regional offices concerning dumping complaints. In October 1987, OIG issued more detailed regional instructions on the handling of dumping complaints. Any complaints received by OIG are to be referred first to both OCR and HCFA, rather than investigated by OIG (although certain facts may be established prior to referral, such as obtaining the name of the facility, name of the complainant, etc.). These instructions indicate that OIG will rely on HCFA's survey to determine if the case is substantiated, and that investigators should pursue a course of action with the CMP negotiator if the case does have merit. No specific instructions for the development of the case for imposition of CMPs are given and no timeframes to impose a CMP have been established; standard procedures are used. A section for investigating dumping complaints is being prepared for the Special Agent Handbook.

Instructions issued at the same time as the October transmittal direct regional OIG personnel to review samples of previously closed cases in HCFA to determine if OIG action is needed on those cases. In practice such reviews have been conducted on a small scale and sporadically; OIG considers this primarily a mechanism to "beat the bushes" for cases in those regions where few allegations of dumping have been substantiated by HCFA and referred to OIG.

In addition, OIG is tracking all allegations of dumping received by HCFA on a monthly basis. Recently meetings have taken place in headquarters with OCR staff to determine how OCR activities might be incorporated in the report to reflect all departmental activity on dumping cases.

OCR Instructions

The OCR's dumping instructions to its ROs are the most recent of all, and in fact were published after we conducted our interviews (April 1988). The new instructions assign a much higher priority to dumping cases than some OCR regions report having assigned them in the past, even though the investigation of dumping cases was listed as one of the Director's national priorities for 1988. For example, in one region, OCR personnel reported that they have relied solely on HCFA's investigation to determine if a case has merit because OCR lacks the necessary medical expertise (although the OCR Director, in comments to the draft of this report, contended that reliance on HCFA's investigation

was to avoid duplicative effort, not because of OCR's lack of access to medical expertise). Similar reliance on HCFA's investigation was documented elsewhere where OCR staff felt that, in addition to the necessary expertise, HCFA also had the better enforcement authority. No particular priority was assigned dumping cases by OCR staff in those regions.

The new instructions, however, state that dumping complaints should be handled on a priority basis, just as AIDS discrimination complaints, although the timeframe for investigating the cases remains the standard 195 days.⁶ In addition, those instructions detail how a compliance review should be conducted. The information to be gathered by the OCR investigator, according to the Model Investigative Plan includes: (1) a copy of hospital's nondiscrimination policy; (2) a description of emergency room services offered; (3) a copy of hospital's written policies and procedures regarding emergency room treatment of various persons; (4) a copy of hospital's written policies and procedures regarding in-patient admission; (5) copies of forms or other written information provided to patients; and (6) patient records from both sending and receiving hospitals identifying emergency room treatments, transfers and releases.

Appendix C contains exhibits displaying each component's instructions to its regional or field offices for responding to complaints of patient dumping.

There are different conceptions within the Department as to what constitutes patient dumping, due to varying authorities under which it might be prosecuted (COBRA, Section 504, title VI).

The OCR's procedures indicate that a dumping complaint may be investigated under a number of different authorities, including section 504 of the Rehabilitation Act of 1973 and title VI of the Civil Rights Act of 1964. These authorities would be invoked if a hospital denied a person emergency services on the basis of race, color, national origin, or a mental or physical handicap. We did not find any evidence in the three regions we visited that a complaint of emergent patient dumping as defined under COBRA has been pursued under these authorities.

Patient dumping is generally considered an economic phenomenon, as in Hill-Burton, where emergency services are denied due to financial factors (inability to pay, lack of insurance). This is primarily the group at which COBRA is aimed. However, COBRA would also cover circumstances in which a patient is denied needed emergency services on a basis other than an economic factor (such as the assumption that a patient is high-risk for the AIDS virus), since COBRA requires screening of *all* patients and treatment of *all* patients in need.

Where a patient is denied emergency services on a basis covered by title VI or section 504 *and is not in medical need*, only OCR would have jurisdiction (as long as the patient was screened to determine if need existed). While OCR's dumping procedures do not include instructions to the regional offices on how to approach non-emergent patient dumping (OCR has indicated

that such procedures are already in place), that area is clearly within OCR's purview and does not overlap with COBRA, which covers only emergent situations.

Steps are being taken to improve coordination among the components, although this has not been a priority in the past.

Meetings have taken place recently at the headquarters and regional level between OI, HCFA, and OCR to discuss the handling and coordination of dumping complaints. These meetings have taken place on the initiative of all involved components. As noted above, recent instructions issued by the central offices of OCR and HCFA to the ROs also indicate that referral of complaints to the other office should take place when a complaint is received.

These steps, although helpful, may not suffice to avoid situations such as that described by one regional office, in which one hospital was subjected to a number of separate visits by HCFA, OCR, and OIG at virtually the same time. The OCR representative at this region indicated that, on the same day he was meeting with obstetrical staff to describe the requirements and implications of the compliance agreement reached between the hospital and OCR, HCFA representatives were "down the hall" asking for additional information to support their investigation. The OIG staff arrived on the site a few days later to determine if imposition of CMPs was warranted. Under current procedures, separate investigations may still occur (although OCR's instructions indicate that the feasibility of pursuing a joint investigation with HCFA should be considered) and this kind of situation could be repeated.

The referral of complaints to other components with jurisdiction has been a particular problem in the past, especially between HCFA and OCR. Several regions commented on the lack of communication between these two components. For example, our case file review indicated that in two regions HCFA referred a number of complaints in batches to OCR only after HCFA instructions were issued to refer cases to OCR. In seven instances where HCFA substantiated a complaint, there is no evidence in the case file that it was referred to the OIG for penalties. In addition, practices appear to vary among the regions as to whether a complaint is referred immediately upon receipt to the other components, or only after a preliminary determination has been made that the complaint has some merit. The new instructions issued by the central offices directly address the question of referrals and should eliminate this problem.

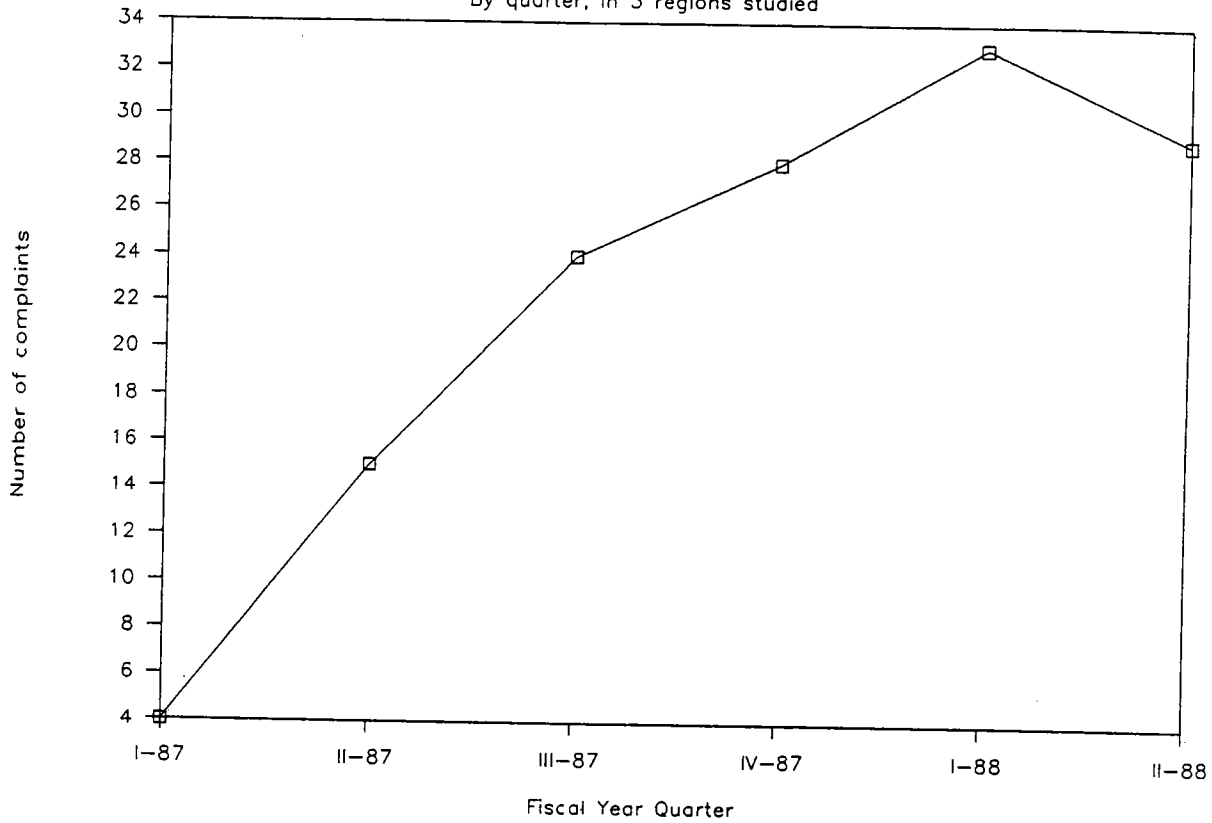
The number of patient dumping complaints received by the Department has steadily increased over time.

As exhibit 1 indicates, in the three regions studied, the Department received four complaints in the first quarter of the Federal Fiscal Year 1987 (October - December 1986); 15 in the second quarter 1987 (January - March 1987); 24 in the third quarter 1987 (April - June 1987); 28 in the fourth quarter 1987 (July - September 1987); 33 in the first quarter 1988 (October - December 1987) and 29 in the second quarter 1988 (January - March 1988).

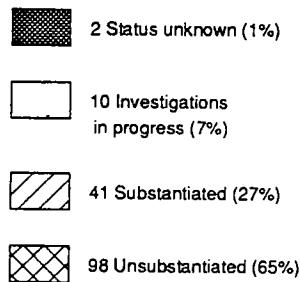
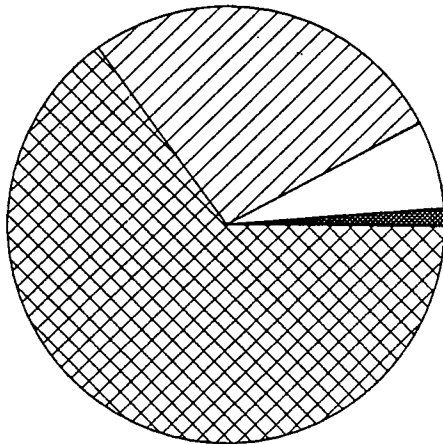
EXHIBIT 1

NUMBER OF COMPLAINTS RECEIVED BY HHS

By quarter, in 3 regions studied



Sixty-five (43 percent) of the total number of complaints in the three regions were received in Region VI. However, the most dramatic increases in caseload occurred in Regions IV and IX. In Region IX, for example, nine complaints were received prior to August 1987. Between August 1987 and April 1988, a 9-month period, an additional 32 complaints were received.



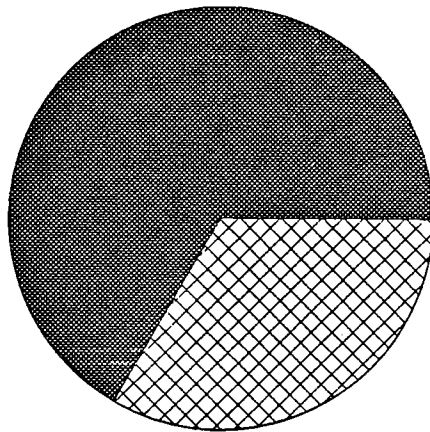
Most complaints investigated by HCFA to date in the three regions studied have been determined to be unsubstantiated. When complaints are substantiated, termination rarely occurs.



Of a total 151 complaints received in the three regions visited, HCFA found 98 cases (65 percent) to be unsubstantiated and 41 (27 percent) to be substantiated. Ten investigations were in progress at the time of our analysis, and the status of two cases was unknown.

Thirty-two termination actions have been initiated by HCFA; in 30 of those cases, hospitals submitted plans of correction and no termination took place. Two hospitals were terminated for COBRA violations, both in Region VI.⁷

From discussions with regional HCFA staff, it appears that termination actions are pursued only where evidence of current noncompliance exists. One HCFA representative indicated that termination actions "won't stand up in court" if the current state of compliance has not yet been determined. Consequently, HCFA considers a plan of correction to be sufficient to cancel a termination action.

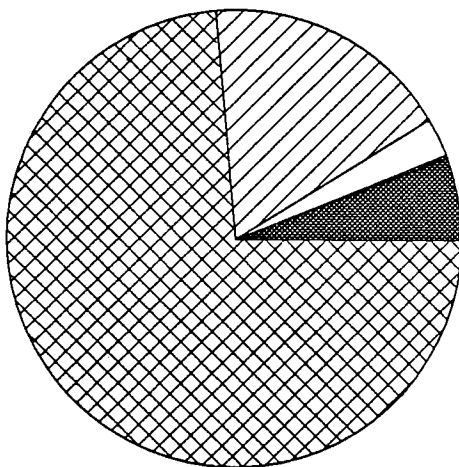
Our analysis reveals wide regional variances, both in substantiating cases and in taking action on substantiated cases. In Region VI, 27 of 65 complaints (42 percent) were found to be substantiated. In Region IV, 5 of 11 complaints (45 percent) were found to be substantiated; the rate was even lower--three out of 41 complaints, or only 7 percent--in Region IX. Regions also varied widely in their response to substantiated complaints. In Region VI, termination actions were initiated in 24 of the 27 (89 percent) substantiated cases. In Region IV, termination actions were initiated in five of the 11 substantiated cases (45 percent), and no actions were initiated in any of Region IX's three substantiated cases.







 22 No jurisdiction (67%)
 11 Pending (33%)

The OCR often lacks jurisdiction and has not yet taken enforcement action on dumping referrals from HCFA in the three regions studied.

In the three regions studied, OCR had not yet taken any enforcement action on cases referred by HCFA. In 22 of the 33 cases (67 percent) referred to OCR by HCFA, OCR determined it did not have jurisdiction. Eleven complaints are pending (which may include active investigations in progress) in OCR in those regions; most received recently.



 2 CMP imposed (6%)
 1 Closed, no action (3%)
 6 In negotiation for settlement (18%)
 25 Investigations in progress (73%)

Many cases substantiated by HCFA are still under investigation by OIG.

The OIG may take action based on past violations, regardless of a hospital's current compliance. In 34 of the 41 cases substantiated by HCFA, documentation of a formal referral to the OIG was found in the file. As of April 1988 in the 3 study regions, 25 of these 34 cases (74 percent) were still under investigation in OIG field offices. Eight cases have been referred to the OIG central office for action, with CMPs imposed in two of those eight cases.

Conversations with OIG staff indicate that the high number of pending cases is primarily due to recent referrals from HCFA (many of the pending cases were received after January 1988), a lack of resources (no additional resources were

authorized in the COBRA legislation for enforcement) and the complicated nature of dumping cases (involving professional medical judgment, requiring medical review, etc.).

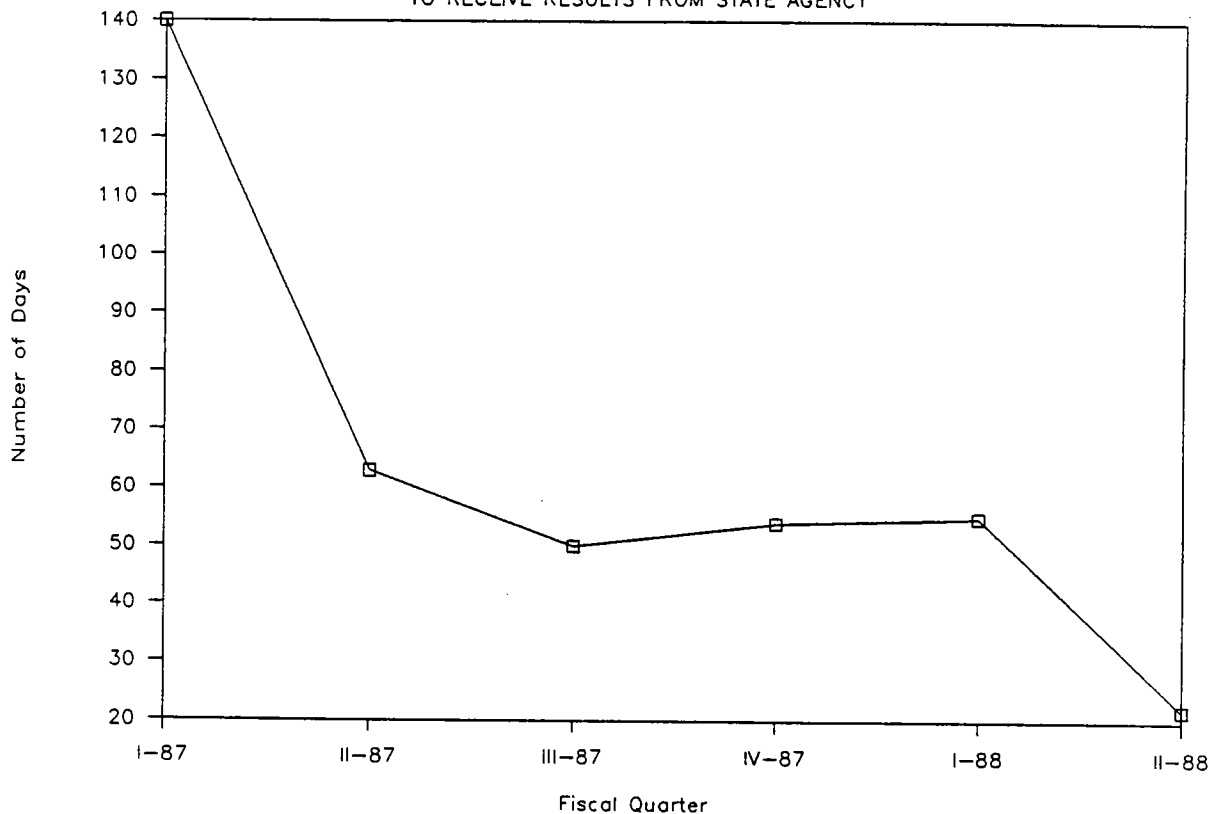
Resolution of dumping complaints is time-consuming.

It has taken an average of over 30 days for HCFA to refer the complaint and receive results from the State agency for cases ultimately found to be substantiated in the three regions studied. The average for cases ultimately found to be unsubstantiated is even higher. However, the average time required for this activity has improved since a year ago (see below).

It has taken anywhere from the same day to 214 days for HCFA to make a formal referral to the OIG for investigation at the regional office level, although the average time required has improved since August 1987 (from 66 to 42 days in Region IV, and from 111 to 37 days in Region VI.)⁸ Of the eight cases referred to the central office, it has taken 42 to 241 days for the regional OIG to complete its investigation and refer the case to the central office for imposition of CMPs or suspension, with two cases taking over 200 days and another three taking over 100 days. In the two cases where CMP settlement has occurred, it has taken 177 and 214 days to reach agreement.⁹

EXHIBIT 2

**AVERAGE TIME REQUIRED FOR HCFA
TO RECEIVE RESULTS FROM STATE AGENCY**



Analysis of OCR timeframes was not conducted due to their limited experience. As indicated earlier, 22 of 33 complaints received in the three regions have been closed because OCR determined it did not have jurisdiction. Of the remaining complaints all are pending, most received on referrals from HCFA after January 1988.

Activities undertaken by the components include data collection and analysis, interviews with patients and hospital staff, and reviews of other patient files to determine if a pattern of abuse exists. Staff interviewed in all three components described these activities as "time-intensive." In one region, OI staff indicated that they expanded their investigation in one hospital when they discovered a pattern of abuse in order to support the imposition of a larger CMP, although they could have recommended the imposition of a smaller CMP earlier based on validation of the original complaint.

RECOMMENDATIONS

The Department should align the responsibilities of component agencies in order to assure a unified response to a single complaint, or series of complaints involving a single hospital, so as to improve response and the efficient resolution of complaints.

Based on our findings, it appears that all involved components are taking productive steps to improve the Department's response to complaints of patient dumping, including the coordination and referral of complaints between components. Even so, as many as three separate investigations of a complaint or a series of complaints involving a single hospital may take place--one by HCFA to determine if a violation of COBRA occurred and the hospital's current state of compliance; one by OIG to further develop HCFA's case to determine if a pattern of abuse by the hospital exists; and one by OCR to determine if a violation of Hill-Burton occurred.

The undertaking of as many as three investigations results in duplicative effort (since all three components rely on similar information to develop the case); inefficient expenditure of resources (three teams instead of one); an inconsistent response by the Department (since all three components may be requesting information and conducting on-site visits at the same time); and a lengthened response time (since OIG begins its own investigation after HCFA's determination that a violation has occurred, for example). Consequently, we recommend that a unified approach be taken to respond to allegations. We recognize that a rapid response to complaints must not be jeopardized, but instead should be supported, by a unified strategy.

The preferred approach to accomplish this objective would require, among other things, that (1) a single notification regarding the commencement of an investigation be made to the hospital and the complainant; (2) a single investigative strategy be pursued to meet the level of proof required (including a determination as to the validity of allegations of past infractions and the current state of compliance by the hospital); (3) a single data request to the hospital be made; (4) a single set of interviews be conducted with hospital staff, the complainant, involved patients, and other relevant parties; and (5) a single notice of determination, outlining conclusions and actions to be taken, be made to the hospital and to the complainant.

The objective of a unified response can be supported in a number of different ways. Among the alternatives are:

- Joint OCR-HCFA investigations could be conducted, as suggested by OCR in its manual for responding to complaints of patient dumping. A single approach could be developed, or investigations could be mapped out on a case-by-case basis, with the component most directly involved taking the lead. The Office of Investigations in OIG should consult with the team to ensure that data gathered will support a determination of whether to impose a CMP or suspend a hospital or physician.

- The OCR could delegate its responsibility for investigating complaints of patient dumping under Hill-Burton to HCFA, since COBRA has a more detailed statutory base and enforcement is stronger under that authority. HCFA has access to more resources (PROs, State agencies) and has more medical expertise with which to judge the validity of patient dumping complaints. Further, as demonstrated by our analysis of the casefile information, most complaints are received at the State agency level, to which HCFA has a direct and pre-existing relationship.

We believe that both these approaches have merit and should be considered. There may be other configurations which support the objectives outlined above, as well.

The HCFA and OCR should pursue legislation to better align their authorities under Hill-Burton and COBRA and to establish a common departmental definition as to what constitutes emergent patient dumping under the relevant provisions of those statutes.

As noted previously in this report, OCR and HCFA may reach different conclusions as to whether a complaint of patient dumping is valid based on their different statutory authorities. For example, lack of medical certification attesting that the benefits outweigh the risks for transfer of an unstable patient is a violation of COBRA, but not of Hill-Burton. This lack of conformity could jeopardize the effectiveness of a unified strategy.

As noted earlier, OCR has authority under Hill-Burton over patient dumping in a non-emergent setting. The authority of OCR in this area does not overlap with HCFA's authority under COBRA and this type of violation should not be included in a common definition of emergent patient dumping. Further, if OCR wishes to bring a discrimination action under title VI or section 504 for actions that may or may not involve emergent patient dumping, it may do so on its own authority, outside the Hill-Burton/COBRA framework to prevent dumping of patients from emergency rooms. Thus we agree with HCFA's comment to our draft report that "OCR should continue to be responsible for [violations of Hill-Burton which do not also violate COBRA]."

In order to develop an efficient and consistent response to complaints, a set of guidelines should be developed by the Department which outlines in detail what actions can be taken (termination, suspension, CMPs, etc.) in response to varying levels of violations (isolated incident, pattern of abuse, evidence of willful negligence, etc.).

As noted in our findings, there are wide variations within HCFA in actions taken in response to substantiated cases. Although HCFA's new draft procedures will support uniformity in action, *all* components should take appropriate measures to ensure that consistent actions are taken in regard to substantiated cases. A set of guidelines, developed in tandem by HCFA, OCR, and OIG, should be developed for use by regional offices outlining the full range of actions that can be taken in response to varying levels of violations, and guidance for making the proper determination.

A set of time frames for investigation and resolution of complaints should be developed, and a screening mechanism (such as the State agency) used to focus investigative resources on more productive cases.

Time frames for investigation and subsequent action should be established, such as those detailed in OCR's April 1988 guidelines, which outline expected deadlines for activities in *all phases* of an investigation from receipt of a complaint to action by the Department. Lastly, since many complaints are unsubstantiated, we support HCFA's use of the State agency to conduct a preliminary, prompt investigation of a complaint before the Department commits significant resources to a full investigation.

END NOTES

1. Office of Inspector General, "Patient Dumping After COBRA: Assessing the Incidence and the Perspectives of Health Care Professionals," OAI-12-88-00830, August 1988.
2. Committee on Government Operations, "Investigation of the Office for Civil Rights in the Department of Health and Human Services," House Report 100-56, April 1987, p. 28.
3. Committee on Government Operations, "Equal Access to Health Care: Patient Dumping," House Report 100-531, March 1988, p. 12.
4. Although the term "investigation" has specific connotations in the investigative community, it is used here as a generic term to mean examination of facts, review or survey. It does not denote any specific process, level of effort or standard of proof.
5. It should be noted that the time frames for the PRO and State Agency are for investigation of the initial complaint, and do not include additional time to expand the scope of the review, if necessary; a HCFA re-review, if HCFA determines that it is unsatisfied with the State investigation; or termination and re-survey to determine if conditions have been corrected.
6. The 195 days are allocated as follows: 15 days for acknowledgement letter to complainant; 75 days for investigation; 15 days to issue letter of findings or letter of warning; 90 days to issue the letter of noncompliance, negotiate a settlement or refer the case for enforcement.
7. Hospitals may re-enter the program after having been terminated, if HCFA determines that the hospital is now in compliance.
8. No substantiated cases were referred to Region IX OIG staff during the study period.
9. The dates used for CMP settlement are the dates on which the necessary paperwork is signed. According to OI, agreement on the terms of the settlement may take place considerably sooner.

APPENDIX A

Hill- Burton Regulation

§ 124.601 Applicability.

The provisions of this subpart apply to any recipient of Federal assistance under Title VI or XVI of the Public Health Service Act that has given an assurance that it would make the facility or portion thereof assisted available to all persons residing (and, in the case of Title XVI assisted applicants, employed), in the territorial area it serves. This assurance is referred to in this subpart as the "community service assurance."

§ 124.602 Definitions.

As used in this subpart—

"Act" means the Public Health Service Act, as amended.

"Facility" means the an entity that received assistance under Title VI or Title XVI of the Act and provided a community service assurance.

"Fiscal year" means facility's fiscal year.

"Secretary" means the Secretary of Health and Human Services or his delegatee.

"Service area" means the geographic area designated as the area served by the facility in the most recent State plan approved by the Secretary under Title VI, except that, at the request of the facility, the Secretary may designate a different area proposed by the facility when he determines that a different area is appropriate based on the criteria in 42 CFR 53.1(d).

"State agency" means the agency of a state fully or conditionally designated by the Secretary as the State health planning and development agency of the State under section 1521 of the Act.

§ 124.603 Provision of services.

(a) *General* (1) In order to comply with its community service assurance, a facility shall make the services provided in the facility or portion thereof constructed, modernized, or converted with Federal assistance under Title VI or XVI of the Act available to all persons residing (and, in the case of facilities assisted under Title XVI of the Act, employed) in the facility's service area without discrimination on the

ground of race, color, national origin, creed, or any other ground unrelated to an individual's need for the service or the availability of the needed service in the facility. Subject to paragraph (b) (concerning emergency services) a facility may deny services to persons who are unable to pay for them unless those persons are required to be provided uncompensated services under the provisions of Subpart F.

(2) A person is residing in the facility's service area for purposes of this section if the person:

(i) is living in the service area with the intention to remain there permanently or for an indefinite period;

(ii) is living in the service area for purposes of employment; or

(iii) is living with a family member who resides in the service area.

(b) *Emergency services.* (1) A facility may not deny emergency services to any person who resides (or, in the case of facilities assisted under Title XVI of the Act, is employed) in the facility's service area on the ground that the person is unable to pay for those services.

(2) A facility may discharge a person that has received emergency services, or may transfer the person to another facility able to provide necessary services, when the appropriate medical personnel determine that discharge or transfer will not subject the person to a substantial risk of deterioration in medical condition.

(c) *Third party payor programs.* (1) The facility shall make arrangements, if eligible to do so, for reimbursement for services with:

(i) Those principal State and local governmental third-party payors that provide reimbursement for services that is not less than the actual costs, as determined in accordance with accepted cost accounting principles; and

(ii) Federal governmental third-party programs, such as medicare and medicaid.

(2) The facility shall take any necessary steps to insure that admission to and services of the facility are available to beneficiaries of the governmental programs specified in paragraph (c)(1) of this section without discrimi-

APPENDIX B

Cobra Regulation

by reviewing discharge plans to ensure that they are responsive to discharge needs.

(Catalog of Federal Domestic Assistance Programs No. 13.773, Medicare—Hospital Insurance; No. 13.714, Medical Assistance)

Dated: September 3, 1987.

William L. Roper,

Administrator, Health Care Financing Administration.

Approved: November 5, 1987.

Otis R. Bowen,

Secretary.

Editorial Note: This document was received for publication at the Office of the Federal Register on June 10, 1988.

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42 CFR Parts 405, 489, 1001 and 1003

[BERC-393-P]

Medicare Program; Participation in CHAMPUS and CHAMPVA, Hospital Admissions for Veterans, Discharge Rights Notice, and Hospital Responsibility for Emergency Care

AGENCIES: Health Care Financing Administration (HCFA) and Office of Inspector General (OIG), HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise requirements for Medicare participating hospitals by adding the following:

- A hospital must provide inpatient hospital services to individuals who have health coverage provided by either the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) or the Civilian Health and Medical Program of the Veterans Administration (CHAMPVA), subject to limitations provided by regulations, and accept the CHAMPUS/CHAMPVA-determined allowable amount as payment in full for the services.

- A hospital must provide inpatient hospital services to military veterans (subject to the limitations provided in 38 CFR 17.50 ff.) and accept payment from the Veterans Administration as payment in full.

- A hospital must give each beneficiary a statement of his or her rights concerning discharge from the hospital.

- A hospital with an emergency department must provide, upon request and within the capabilities of the hospital, an appropriate medical screening examination and stabilizing treatment to any individual with an emergency medical condition and to any woman in active labor, regardless of the individual's eligibility for Medicare.

HCFA would provide for the termination of a provider's agreement for violation of any of these provisions. In addition, OIG would provide for suspension of a provider's agreement and for civil monetary penalties for violation of the emergency care provision.

These revisions would implement sections 9121 and 9122 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (as amended by section 4009 of the Omnibus Budget Reconciliation Act of 1987), section 233 of the Veterans' Benefit Improvement and Health Care Authorization Act of 1986, and section 9305(b)(1) of the Omnibus Budget Reconciliation Act of 1988.

DATE: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on August 15, 1988.

ADDRESS: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-393-P, P.O. Box 26676, Baltimore, Maryland 21207.

Please address a copy of comments on information collection requirements to: Allison Herron, EOMB Desk Officer for HCFA, Office of Information and Regulatory Affairs, Room 3002, New Executive Office Building, Washington, DC 20503.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Ave. SW., Washington, DC, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

In commenting, please refer to file code BERC-393-P.

Comments received timely will be available for public inspection as they are received, which generally begins about three weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION CONTACT:

Thomas Hoyer, 301-966-4607. For all provisions except suspensions and civil monetary penalties.

Jim Patton 301-965-9601. For provisions relating to suspensions and civil monetary penalties.

SUPPLEMENTARY INFORMATION:

I. Background

A. Participation in the CHAMPUS and CHAMPVA Programs

CHAMPUS (Civilian Health and Medical Program of the Uniformed Services) and CHAMPVA (Civilian Health and Medical Program of the Veterans Administration) programs pay for health care services furnished to dependents and survivors of military personnel, of retirees and their dependents, and of veterans. Generally, the programs have paid hospitals based on their charges. Section 931 of the Department of Defense Authorization Act, 1984 (Pub. L. 98-94) authorized these programs to pay (to the extent practicable) for inpatient hospital services using Medicare reimbursement procedures. Because the Medicare prospective payment system (PPS) (the system whereby we pay a hospital a predetermined amount based on the patient's diagnosis and any surgical procedures performed, rather than by the number of days hospitalized) results in Medicare cost savings, the Department of Defense (DoD) expects that it would realize similar savings if it were to use a model similar to Medicare's PPS. Paying on the basis of a fixed rate appropriate to the particular diagnosis involved has been shown to be an equitable method of paying for hospital care. Therefore, the Office of Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS) has published a final rule which includes provisions for the implementation of a DRG-based payment system modeled after Medicare's PPS for CHAMPUS inpatient hospital admissions occurring on or after October 1, 1987 (52 FR 32992).

Hospitals that furnish services to CHAMPUS and CHAMPVA beneficiaries are authorized to provide services to these beneficiaries following an approval process similar to that used for Medicare participation. All hospitals certified by the Joint Commission on Accreditation of Health Care Organizations (JCAHO) are authorized providers; any Medicare hospital may be (and all have been thus far) deemed to be authorized providers. All others are surveyed by OCHAMPUS to determine whether they are authorized providers.

"Participation" has a different meaning for CHAMPUS and CHAMPVA than for Medicare; providers have been able to decide on a case-by-case basis whether to "participate" in the program and thus accept the CHAMPUS/CHAMPVA-determined allowable amount as payment in full (under these

programs, beneficiaries are required to pay a cost-share for each hospital admission, and this is considered to be separate from the CHAMPUS/CHAMPVA payment). Under Medicare, hospitals must agree to bill the program for all beneficiaries and accept Medicare payment as payment in full (less applicable deductibles, coinsurance amounts, and noncovered items).

As indicated above, all Medicare hospitals are also authorized providers in CHAMPUS and CHAMPVA on the basis of their JCAHO-approved status or are deemed authorized providers based on their Medicare-approved status. The benefits to the DoD of requiring them to be paid either under a DRG-based payment system or based on reasonable cost are lost, however, if the hospitals can selectively participate in the CHAMPUS and CHAMPVA programs. Congress, in section 9122 of COBRA, now requires all Medicare hospitals, beginning January 1987, to participate in CHAMPUS or CHAMPVA as authorized providers (i.e., they must bill CHAMPUS or CHAMPVA and accept the CHAMPVA/CHAMPUS-determined allowable amount as payment in full—less applicable deductible, patient cost-share, and noncovered items).

B. Participation in the Veterans Administration (VA) Health Care Program

A retired veteran with a service-connected disability is not required to use Veterans Administration (VA) hospitals but may elect to receive services from "civilian" providers and be reimbursed through CHAMPUS. However, once the VA has made or has authorized payment for services related to a service-connected disability, the veteran is to obtain all services through the VA. In cases where the veteran receives services from a non-VA hospital, either through choice or because there is no available VA hospital which can provide the necessary services, the VA pays for the services based on the hospital's charges.

As with CHAMPUS and CHAMPVA, when they also paid the hospital's charges, this type of payment is more expensive than payment on a prospective basis or based on reasonable costs. As a result, the VA is setting up a national prospective payment system.

To alleviate hospital expenses for the VA, Congress passed section 233 of the Veterans' Benefit Improvement and Health-Care Authorization Act of 1986 (Pub. L. 99-576). This section requires Medicare hospitals to be participating providers of medical care to veterans

eligible to receive care at the hospital. The hospital then would receive payment for the services under the applicable VA payment system, rather than simply on the basis of the hospital's charges.

C. Statement of Beneficiary Rights

After the prospective payment system became effective for the Medicare program, we began to hear allegations that Medicare beneficiaries were discharged too early from the hospital and we also began to receive complaints that patients did not understand their rights as Medicare beneficiaries in cases where they were advised that discharge was appropriate but they disagreed. On April 17, 1985, 42 CFR 466.78(b)(3) was revised requiring all hospitals to provide Medicare beneficiaries with information about PRO review, including their appeal rights (50 FR 15331). In further response to concerns about early discharges and lack of adequate appeal information, we began requiring hospitals to furnish each beneficiary upon admission a specific statement developed by HCFA (i.e., the "Important Message from Medicare") telling a beneficiary of his rights to be fully informed about decisions affecting Medicare coverage or payment and about appeal rights in response to any hospital notices to the effect that Medicare will no longer cover the care. The "Message" we developed also advises the patient what to do when he receives such a hospital statement and how to elicit more information. The requirements relating to the "Important Message from Medicare" were incorporated into the program's operating instructions.

Congress subsequently passed section 9305(b) of the Omnibus Budget Reconciliation Act of 1986 (OBRA 86). Now, as part of its participation agreement with Medicare, each hospital must agree to furnish each Medicare beneficiary with a notice, at or about the time of admission, that explains the patient's rights in detail.

D. Responsibilities of Medicare Participating Hospitals in Emergency Cases

Hospitals that choose to participate in the Medicare program agree in writing to meet various requirements included in section 1866 of the Social Security Act (the Act). Before enactment of Pub. L. 99-272 on April 7, 1986, the Act did not specifically address the issue of how hospitals with emergency medical departments must handle individuals who have emergency medical conditions or who are in active labor.

In its Report accompanying H.R. 3128, the House Ways and Means Committee indicated that Congress was concerned about the increasing number of reports that hospital emergency rooms are refusing to accept or treat patients with emergency conditions, including medically unstable patients, if the patients do not have medical insurance. In addition, the Report stated that there have been reports that patients in an unstable condition have been transferred improperly, sometimes without the consent of the receiving hospital. Because Congress believed that this situation may have worsened since the Medicare prospective payment system for hospitals became effective, the Report states that the Committee "wants to provide a strong assurance that pressure for greater hospital efficiency are not to be construed as license to ignore traditional community responsibilities and loosen historic standards." (H.R. Rep. No. 99-241, 99th Cong., 1st Sess. 27 (1985).) As a result of this concern, Congress enacted section 9121 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985, Pub. L. 99-272.

II. Legislation

A. Participation in CHAMPUS and CHAMPVA Programs

Section 9122 of COBRA amended section 1866(a)(1) of the Act by adding a new paragraph (J), which requires hospitals in the Medicare program to be participating providers of medical care, for inpatient services only, under any health plan contracted for under 10 U.S.C. 1079 or 1086 (CHAMPUS) or under 38 U.S.C. 613 (CHAMPVA), in accordance with admission practices and payment methodology and amounts as prescribed under joint regulations issued by the Secretaries of Health and Human Services, Defense and Transportation. This requirement applies to services furnished to CHAMPUS and CHAMPVA beneficiaries admitted on or after January 1, 1987.

(Section 9122 of COBRA also required that the legislation apply to all agreements entered into on or after April 7, 1986, but this requirement was deleted by section 1895(b)(6) of the Tax Reform Act of 1986 (Pub. L. 99-514), enacted October 22, 1986.)

B. Participation in the Veterans Administration Health Care Program

Section 233 of the Veterans' Benefit Improvement and Health-Care Authorization Act of 1986 (Pub. L. 99-576) was enacted on October 28, 1986. It

added a new paragraph (L) to section 1866(a)(1) of the Act. It requires hospitals that participate in Medicare to be participating providers under 38 U.S.C. 603, in accordance with the admissions practices, and payment methodology and amounts, prescribed under joint regulations issues to implement this section by the Secretary of HHS and the Administrator of the VA. This provision applies to services furnished to veterans admitted on or after July 1, 1987.

C. Statement of Beneficiary Rights

The Omnibus Budget Reconciliation Act of 1986 (OBRA 86) was enacted on October 21, 1986. Section 9305(b)(1) of OBRA 86 adds a new paragraph (M) to section 1866(a)(1) of the Act. That paragraph puts current regulatory and administrative policies into statute and requires a hospital that is eligible to participate in the Medicare program to agree to furnish, upon admission, a beneficiary, or an individual acting on his or her behalf, with a written statement of the beneficiary's discharge rights. The Statement must explain:

(1) The individual's rights to benefits for inpatient hospital services and for posthospital services under Medicare;

(2) The circumstances under which the beneficiary will and will not be liable for charges for continued stay in the hospital;

(3) The beneficiary's right to appeal denials of benefits for continued inpatient hospital services, including the practical steps to initiate the appeal

(4) The individual's liability for services if the denial of benefits is upheld on appeal; and

(5) Additional information that the Secretary specifies.

Section 9305(b)(2) of OBRA 86 requires that we prescribe the language to be used in the statement not later than six months after the effective date of OBRA 86. After we have developed the revised language for the statement required under OBRA, the hospitals must begin complying with the requirement to give the revised statement to beneficiaries upon admission.

D. Responsibilities of Medicare Participating Hospitals in Emergency Cases

The Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 was enacted on April 7, 1986. Section 9121 prohibits hospitals with emergency medical departments from refusing to treat medically unstable patients. It also contains provisions designed to halt the inappropriate transfers of these patients to other medical facilities.

Section 9121 of COBRA added a paragraph (i) to section 1866(a)(1) of the Act and added a new section 1867 to the Act. Section 1866(a)(1)(I) requires that a hospital participating in the Medicare program must agree to comply with the requirements of section 1867 of the Act to the extent applicable. Section 1867 provides the following:

(a) A hospital with an emergency department must, within the capabilities of its emergency department, provide an appropriate medical screening examination to any individual who comes to the emergency department for examination or treatment of a medical condition or of active labor and on whose behalf the examination or treatment is requested; the purpose of the examination is to determine whether the individual has an emergency medical condition or is in active labor. This requirement applies regardless of the individual's eligibility for Medicare benefits.

(b) If an individual, regardless of eligibility for Medicare benefits, has an emergency medical condition or is in active labor, the hospital must either provide for further examination and treatment (within its capabilities) or make an appropriate transfer of the patient to another medical facility, unless the treatment or transfer is refused.

(c) A hospital may not transfer a patient unless—

(1) (A) He or she, or a legally responsible person acting on his or her behalf, requests the transfer, or (B) a physician, or other qualified medical personnel when a physician is not readily available, has certified that the medical benefits expected from the treatment at the new facility outweigh the increased risks to the patient's condition resulting from the transfer; and

(2) The transfer is an "appropriate transfer", as defined below.

An "appropriate transfer" is a transfer: (1) in which the receiving facility has available space and qualified personnel for the treatment of the patient and has agreed to accept the transfer and to provide appropriate medical treatment; (2) in which the transferring hospital provides the receiving facility with appropriate medical records (or copies) of the examination and treatment furnished at the transferring hospital; (3) in which the transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer; and (4) that meets other requirements as the Secretary may find necessary in the

interest of the health and safety of the patient.

(d) A hospital that fails to meet the requirements of section 1867 of the Act—

(1) Is subject to termination of its Medicare agreement or, at the option of the Secretary of the Department of Health and Human Services (HHS), suspension of the Medicare agreement if it knowingly and willfully, or negligently, fails to comply with section 1867. The suspension is subject to reasonable notice to the hospital and the public and is for a duration that the Secretary determines to be appropriate; and

(2) Is also subject to civil monetary penalties (which are in addition to those provided under section 1128A of the Act) if it knowingly violates section 1867. The penalty cannot exceed \$25,000 for each violation committed between August 1, 1986 (the effective date of the amendment) and December 21, 1987, or \$50,000 for violations on or after December 22, 1987. (The amount was raised by section 4009(a)(1) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203), effective December 22, 1987.) Each responsible physician is also subject to a civil money penalty of not more than \$25,000 for each knowing violation (\$50,000 for violations on or after December 22, 1987). A responsible physician may also be excluded from Medicare participation for up to five years.

"A responsible physician" is a physician within the meaning of section 1861(r)(1) of the Act (doctor of medicine or osteopathy) who is employed by, or under contract with, the participating provider and acting as such has professional responsibility for the provision of examination or treatment of the individual, or transfer of the individual.

(e) If a hospital violates the requirements of section 1867 and a patient suffers personal harm as a direct result, he or she may, in a civil action against the participating hospital, obtain damages for personal injury under the law of the State in which the hospital is located and may obtain such equitable relief as is appropriate.

(f) Any medical facility that suffers a financial loss as a direct result of a participating hospital's violation of section 1867 may obtain damages available in a civil action against the participating hospital, under the law of the State in which the hospital is located, and may obtain such equitable relief as is appropriate.

(g) No civil action under (e) and (f) above may be brought more than two

years after the date of the violation with respect to which the action is brought.

(h) Section 1867 also contains definitions of several other terms: "emergency medical condition," "participating hospital," "active labor," "to stabilize," "stabilized," and "transfer."

(i) The provisions of section 1867 do not preempt any State or local law except where they directly conflict.

III. Provisions of the Proposed Regulations

A. Participation in CHAMPUS and CHAMPVA programs

We would revise § 489.20, Basic commitments, to show that a participating Medicare hospital must agree to participate in the CHAMPUS and CHAMPVA programs and accept the CHAMPUS/CHAMPVA-determined allowable amount as payment in full in accordance with a new § 489.25, which incorporates statutory provisions.

In a new section, 42 CFR 489.25, we would require Medicare participating hospitals to be participating providers in the CHAMPUS and CHAMPVA programs. We would require the hospitals to comply with Department of Defense regulations governing admissions practices and payment methodology and amounts for such services. (Those regulations would be issued jointly by the Secretaries of Defense, Transportation and Health and Human Services; CHAMPUS has published a final rule that contains provisions for the implementation of a DRG-based payment system, as mentioned earlier.) We would continue the policy that hospitals participating in CHAMPUS and CHAMPVA that also participate in Medicare must meet all Medicare conditions of participation. Thus, if CHAMPUS or CHAMPVA have requirements for participating that differ from Medicare's, Medicare's requirements would have to be met.

We would require hospitals to accept the CHAMPUS/CHAMPVA-determined allowable amount as payment in full for the services provided to these beneficiaries (less applicable deductible, patient cost-share, and noncovered items).

In addition, we would add a new paragraph (11) to § 489.53, Terminations by HHS, to show that a hospital that does not meet the requirements of § 489.25 would be subject to possible termination. We do not anticipate that Medicare participating hospitals will refuse to accept CHAMPUS or CHAMPVA beneficiaries under these proposed requirements. Should one do so, we would expect appropriate

officials from the Department of Defense or Transportation to notify us and we would then discuss the issue with the hospital in hopes of resolving it. If it cannot be resolved, the HCFA regional office would terminate the hospital's provider agreement under the provisions of 42 CFR Part 489, Subpart E, since the hospital's refusal to participate in the CHAMPUS or CHAMPVA programs would violate 42 CFR 489.25 of these regulations.

These revisions would apply only to inpatient hospital services furnished to beneficiaries admitted on or after January 1, 1987.

B. Participation in the Veterans Administration Health Care Program

To implement section 233 of Pub. L. 99-576, we propose to add a new § 489.26. Hospitals do not enter into participation agreements with the Veterans Administration program as they do if they choose to participate in the Medicare program or the CHAMPUS or CHAMPVA programs. Instead, the VA authorizes payment for the treatment, usually on a pre-admission basis at a designated hospital that furnishes the service. We would require a Medicare participating hospital to admit any veteran whose hospitalization is authorized by the VA under 38 U.S.C. 603 (this includes emergency cases, which may be authorized after admission). The hospital would have to meet the requirements of 38 CFR Part 17 regarding admission practices and payment methodology and amounts. This arrangement would not affect the hospitals' need to meet all Medicare hospital conditions of participation.

We would also revise § 489.20, Basic commitments, to require hospitals to admit veterans whose admission is authorized under 38 U.S.C. 603 and to meet the requirements of § 489.26.

We would also revise § 489.53, Termination by HCFA, to show that HHS may terminate any hospital that fails to meet the requirements of § 489.26. This would be included with the paragraph (11) requiring hospitals to participate in CHAMPUS and CHAMPVA.

As with the CHAMPUS and CHAMPVA programs, we do not anticipate that Medicare participating hospitals will resist the requirement to admit veterans. Should one do so, we would expect the appropriate official of the Veterans Administration to notify us and we would then discuss the issue with the hospital in hopes of resolving it. If it cannot be resolved, the HCFA regional office would terminate the hospital's provider agreement under the provisions of 42 CFR Part 489, Subpart E,

since the hospital's refusal to admit veterans violates 42 CFR 489.26 of these regulations.

The VA is developing the regulations necessary to implement the statute (e.g., regarding payment methodology).

These regulations would apply to inpatient services furnished to veterans admitted on or after July 1, 1987.

C. Statement of Beneficiary Rights

We would add a new section, 42 CFR 489.27, to require participating hospitals that furnish inpatient hospital services to Medicare beneficiaries to give every beneficiary (or individual acting on his or her behalf) at or about the time of admission the "Important Message from Medicare." We would not specify the contents of the "Message" in these regulations, as the hospital will not be responsible for writing it; we will distribute to the hospitals the "Message" that the hospitals are to use.

We expect the "Important Message from Medicare" to be available before this rule becomes final. The law is self-implementing, and it requires the language for the statement to be prescribed within six months of the enactment of the legislation and distributed by hospitals within two months after it is prescribed. This rule would merely conform the regulations to the statute.

We have revised the earlier "An Important Message from Medicare" to incorporate the statutory requirements and have solicited comments from major beneficiary and provider organizations, such as the Gray Panthers, the American Hospital Association and the American Association of Retired Persons. We have also sent the "Message" to both the Senate and House Select Committees on Aging. The input from the various entities have been valuable in determining the final version of the "Message"

We would require the hospital to obtain a separate signed acknowledgement from the beneficiary attesting to the receipt of the "Important Message from Medicare" and to retain a copy of the acknowledgement. Effective with admissions on and after March 24, 1986, peer review organizations (PROs) have been required to monitor each hospital to assure that the hospital distributes "An important Message from Medicare" to all Medicare beneficiaries. However, in practice, it has been very difficult for PROs to monitor the issuance of "An Important Message from Medicare" due to a lack of documentation (i.e., the "Message" is given to the beneficiaries generally with several other informational materials

upon admission but there is no record of the transaction). We have received complaints that in some instances beneficiaries have not received the "Message", were not aware that they received, it, and/or did not realize its significance. It has been suggested, and we agree, that requiring the beneficiary to sign a separate, signed acknowledgement attesting to the receipt of the "Message" is a better means of assuring that he or she knows that this is an important document that should be reviewed. Therefore, we are proposing that the hospital be required to obtain the beneficiary's separate, signed acknowledgement attesting to the receipt of the "Message", and to retain a copy of the acknowledgement. We believe that this is important both to assure that the beneficiary receives and is aware of the significance of "An Important Message from Medicare" and to assure that the distribution of it can be monitored. As is always the case with a notice of proposed rulemaking, we seek public comment on this proposed requirement.

We would also revise § 489.20, Basic commitments, to show that a hospital must distribute the "Important Message from Medicare".

We would add a new paragraph (12) to § 489.53, Terminations by HHS, to show that a hospital failing to meet the requirements of § 489.27 may be terminated. Whether or not HHS would terminate a provider would depend on HCFA's judgement as to the scope of the failure and the hospital's correction or plan for correction of the failure. We do not anticipate any hospital opposition to the requirement that the "Message" be distributed. We believe we already have full cooperation from hospitals.

These revisions would apply only to Medicare admissions beginning after we have distributed "An Important Message from Medicare".

D. Hospital Emergency Care

The revisions to the regulations we are proposing would be revisions and additions to 42 CFR Part 489, Provider Agreements under Medicare, and revisions to 42 CFR Part 1001, Program Integrity—Medicare, and Part 1003, Civil Money Penalties and Assessments. Basically, the provisions would parallel the statute.

1. Requirements for Hospitals with Emergency Care Departments

a. We would revise 42 CFR 489.20, which discusses basic commitments, by adding a new paragraph to require hospitals with emergency departments, as part of their participation agreement, to agree to comply with the new

§ 489.24, which incorporates the statutory requirements.

b. We would add a new § 489.24, Special responsibilities of Medicare hospitals in emergency cases, to set forth requirements for emergency cases for all hospitals that have provider agreements with Medicare. We would require a hospital to take the following measures.

i. Medical Screening Requirement. For any individual, regardless of his or her eligibility for Medicare, for whom emergency treatment or examination is requested, we would require a hospital with an emergency department to provide for an appropriate medical screening examination within the emergency department's capability to determine whether an emergency medical condition exists or whether the individual is in active labor, as defined below. The examinations would have to be conducted by individuals determined qualified by hospital by-laws and who meet the Medicare requirements of 42 CFR 482.55, which are that emergency services be supervised by a qualified member of the medical staff and that there be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

We would allow hospitals maximum flexibility in their utilization of emergency care personnel by not including specific requirements concerning education or credentials for individuals conducting emergency medical examinations. This policy is consistent with the specified intent of the conditions of participation (51 FR 22010; 42 CFR Part 482).

ii. Necessary Stabilizing Treatment for Emergency Medical Conditions and Active Labor. If the individual has an emergency medical condition or is in active labor, the hospital would have to provide either further medical examination and treatment to stabilize the medical condition or treatment of the labor or transfer the individual appropriately to another medical facility. We would not hold the hospital responsible if the individual, or a legally responsible person acting on the individual's behalf, refuses to consent in writing to the further examination and treatment or the appropriate transfer to another hospital.

Under these provisions, the hospital is responsible for treating and stabilizing any individual, regardless of eligibility for Medicare, who presents himself or herself with an emergency condition at the hospital, and for providing such care until the condition ceases to be an emergency or until the patient is properly transferred to another facility.

We interpret this to mean, for example, that if a hospital were to admit and then transfer a patient before his or her condition is stabilized, except as provided below, it would be a violation of section 1867 of the Act.

iii. Transfers and Restrictions. If an individual at a hospital has an emergency medical condition that has not been stabilized or the individual is in active labor, the hospital could not appropriately transfer the individual unless one of the following conditions exist:

- The individual (or a legally responsible person on the individual's behalf) requests the transfer.
- A physician (or other qualified medical personnel if a physician is not readily available in the emergency department) has certified in writing that, based upon the reasonable risks and benefits to the individual and the information available at the time, the medical benefits reasonably expected from the provision of appropriate medical treatment at the other facility outweigh the increased risks to the individual's medical condition from the transfer.

We would consider a transfer to be appropriate only if the receiving medical facility has available space and qualified personnel for the treatment of the individual and has agreed to accept transfer of the individual and to provide appropriate medical treatment. The transferring hospital would have to furnish the receiving medical facility with timely appropriate medical records (or copies) of the examination and treatment provided by the transferring hospital. The patient would have to be accompanied by qualified personnel during the transfer; transportation arrangements would have to include the use of necessary and medically appropriate life support measures.

Although the statute authorized the Secretary to find that the transfer must meet "other requirements" in the interest of the health and safety of patients transferred, we are not at this time proposing to adopt any. We do however specifically invite public comment concerning any "other requirements" the Secretary should consider adopting regarding the health and safety of emergency department patients being transferred between medical facilities.

iv. Definitions. We would include in 42 CFR 489.24 the following definitions as included in the statute, without interpretation:

- "Active labor" means labor at a time when delivery is imminent, there is inadequate time to effect safe transfer to

another hospital before delivery, or a transfer may pose a threat to the health and safety of the patient or the unborn child.

- An "emergency medical condition" means a medical condition manifested by acute symptoms of sufficient severity (including severe pain) that the absence of immediate medical attention could reasonably be expected to result in: (a) Placing the patient's health in serious jeopardy; (b) serious impairment to bodily functions; or (c) serious dysfunction of any bodily organ or part.

- "To stabilize" means, with respect to an emergency medical condition, to provide the medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from the transfer of the individual from a facility.

- "Stabilized" means, with respect to an emergency medical condition, that no material deterioration of the condition is likely, within reasonable medical probability, to result from the transfer of an individual from a facility.

- "Transfer" means the movement (including the discharge) of a patient to outside a hospital's facilities at the direction of any person employed by (or affiliated or associated with, directly or indirectly) the hospital, but it does not include moving a patient who has been declared dead or who leaves the facility without the permission of any person responsible for directing transfers.

For the purpose of these definitions, the term "hospital" means a Medicare facility certified as a hospital with its own provider number.

We would not define "participating provider" in Part 489. This is because 42 CFR 400.202 defines terms applicable to all of 42 CFR Chapter IV and already defines "provider". A provider by definition agrees to participate in Medicare. The agreement is written and requires the provider to fulfill certain obligations. Until recently, the existing version of the provider agreement specified provider requirements through a series of references to sections of the law and regulations applicable to these issues; however the COBRA changes made it necessary to update these references to include the new provisions. In December 1986, we revised the provider agreement forms and sent the revised forms to all participating hospitals to sign. The revised forms were accompanied by a letter explaining the new provisions of law that affect the obligations of providers. (Although not all agreements have been returned signed to us, section 1895(b)(4) of the Tax Reform Act of 1986 (Pub. L. 99-514) amended section:

1867(e)(3) of the Act to make it clear that providers did not have to execute a new written agreement specifically to obligate them to comply with section 1867. Rather, the hospitals are obligated to comply with the requirements of section 1867 by virtue of the statute and their current agreements.)

We would add a definition of "participating hospital" and the remaining statutory definition, that of "responsible physician", to 42 CFR Chapter V (Parts 1001 and 1003), since these terms are used in conjunction with monetary penalties, which is under the jurisdiction of the Office of Inspector General. We discuss the definition of "responsible physician" below under "Civil Monetary Penalties."

We invite public comment regarding all definitions.

c. We propose to amend 42 CFR Parts 489, 1001 and 1003 to provide for types of sanctions that would be applied by the Department, as appropriate:

i. *Resolution of Allegations and Determination of Liability.* If the evidence available establishes that a hospital knowingly and willfully, or negligently, failed to provide the appropriate screening and treatment or transfer as explained above, it would be subject to either termination of its provider agreement by HCFA or suspension of its provider agreement by the OIG in accordance with section 1866(b) of the Act. In addition, the OIG can also impose civil money penalties (CMPs) for knowing violations.

When the Department receives a complaint, or any information or allegation, to the effect that a Medicare hospital did not appropriately comply with the emergency medical screening, stabilizing, treatment or transfer requirements, HCFA would, upon receipt of all available information and evidence, conduct sufficient review to determine whether the complaint falls within the jurisdiction of section 1867. If so, HCFA would consider the complaint a substantial allegation and would investigate the allegation thoroughly.

HCFA would send each complainant a letter acknowledging receipt of the complaint, advising him or her of his or her rights to consider independently the civil enforcement provisions of section 1867 and stating that it will refer the complaint to other agencies if during the complaint investigation, it determines that the matter falls under the jurisdiction of other agencies. Thus, HCFA would refer a complaint to the Office of Civil Rights if it determines that a hospital may be in violation of the Hill-Burton Subpart G Community Service regulations at 42 CFR 124.603(b)(1), which require Medicare

participating hospitals that receive Hill-Burton construction grants and loans to provide emergency medical services to any person who resides (or, in the case of some hospitals, works) in the hospital's designated health service area. HCFA would of course inform complainants of the outcome of its investigations.

HCFA would notify State Medicaid authorities, State licensing bodies, the Office of Inspector General, appropriate Peer Review Organizations and the Office of Civil Rights concerning all complaint investigations and all termination actions.

HCFA would determine whether the hospital knowingly and willfully, or negligently, failed to comply with the requirement of § 489.24 based on evidence of (i) inadequate treatment or treatment not being provided; (ii) patients in unstable condition or in active labor not being properly transferred as defined in § 489.24(d)(2); (iii) the hospital's actions, or lack of actions, causing a patient's or infant's death or serious or permanent impairment to a patient's bodily functions; or (iv) a hospital's actions placing a patient's health in serious jeopardy. HCFA would determine the hospital negligent if the hospital and its personnel failed to exercise care that should normally be supplied to a patient experiencing an emergency medical condition or active labor as defined in § 489.24(b).

ii. *Termination of a provider agreement by HCFA.* HCFA's termination authority under this provision is designed so that quick action may be taken to protect the Medicare program, its beneficiaries and other individuals from any potential harm. The termination of a provider agreement would be the initial action contemplated against a hospital that knowingly and willfully, or negligently, failed to meet the requirements set forth in § 489.24. This section would allow for the termination of the hospital's provider agreement under Medicare in accordance with section 1866(b) of the Act. The termination requirement would be contained in § 489.24 as paragraph (e). (The authority to terminate has been delegated from HHS through the HCFA Administrator to HCFA Regional Offices.)

HCFA would revise 42 CFR 489.53, Termination by HCFA, to include in paragraph (b) failure to comply with the requirements of § 489.24 as a mandatory cause for termination of a provider agreement. HCFA would also revise paragraph (c) to state that, if it determines that a hospital is in violation

of § 489.24(a) through (d), HCFA would consider the violation to pose an immediate and serious threat to the health and safety of persons presenting themselves to the hospital for emergency services and would terminate the hospital's approval for Medicare participation within 2 days of the determination unless the violation is corrected.

In those instances in which HCFA determines that a hospital is in violation of the requirements of the Act, it will initiate termination action. When that action is resolved, HCFA will refer the case to the OIG for possible imposition of CMPs. If the OIG, upon further investigation, discovers past violations that did not form the basis of the termination action, it may decide that a sanction is warranted and could exercise its authority to impose a suspension against the reinstated provider. (See section D.3.c. below.)

In instances where HCFA finds no violation, and therefore does not take an action, the closed case would still be transmitted to the OIG. If the OIG, upon reviewing the case file, believes that further case development is warranted, it would be free to do so. If OIG's investigation indicates that there are additional violations that are not reflected in HCFA's case file, it would refer the new case information back to HCFA with a recommendation that HCFA terminate the hospital's provider agreement based on the new findings.

Whether or not HCFA takes a termination action on a given case, all investigated cases will be referred to the OIG for possible imposition of CMPs.

iii. Suspension of a provider agreement by the OIG Termination and suspension of provider. Agreements are mutually exclusive remedies: a given violation or a group of violations of section 1867 of the Act may give rise to termination or suspension, but not both. However, if HCFA has proposed to terminate, or has terminated, the provider agreement of a hospital based on one or more specific violations of section 1867, the OIG is not precluded from suspending that hospital's provider agreement at a later date if, upon further investigation, OIG determines that there are other violations of section 1867 indicating that (1) the pattern of dumping is more widespread than HCFA initially believed, or (2) the additional instances of dumping are so egregious that the penalty of suspension is appropriate.

When it is determined that a hospital's provider agreement should be suspended, the OIG would, in accordance with its notice and appeals procedures set forth in §§ 1001.100

through 1001.115, give notice to the hospital and the public; the suspension would become effective fifteen days after the date of the notice. The hospital would be able to appeal the suspension before an administrative law judge of the Office of Hearings and Appeals of the Social Security Administration. The suspension would be for a minimum of 30 days.

The notice to the hospital would specify:

- The legal and factual basis for the determination;
- The effective date;
- That the duration of the suspension would be for a minimum of 30 days and that during the suspension period, the hospital must demonstrate that further incidents will not occur or the suspension will continue;
- That in addition to denial of payment for Medicare claims, claims for Medicaid payments will not be paid for the care of Medicaid recipients during the period the provider agreement is suspended;
- That the provider will have the opportunity to be reinstated after the suspension, in accordance with §§ 1001.105 through 1001.114;
- The payment policy in effect during the suspension; and
- The appeal rights of the hospital.

For hospitals paid under the prospective payment system, we propose to pay for all covered services furnished to Medicare beneficiaries admitted before the suspension is effective, including payment for a maximum of 30 days after the suspension becomes effective for those cases that qualify as day outliers. On the other hand, we would not make any payment for inpatient hospital services furnished to patients who are admitted on or after the effective date of suspension.

For hospitals reimbursed under the reasonable cost system, no payment will be made for services provided to persons admitted during the suspension period.

Note: The date of admission is not significant for reasonable cost hospitals.

We are proposing to add a new § 1001.202 to reflect the above policy concerning suspension and we are proposing to make the necessary technical changes to §§ 1001.211 and 1001.221.

- We propose to add a new section, § 1001.203, to give the provider procedures to follow when it is suspended and wishes to be reinstated into the Medicare program.

iv. Civil Monetary Penalties. General.

- In addition to termination or suspension of the provider agreement, if a hospital knowingly violates the requirements concerning screening, treatment and transfer, OIG could also impose a civil money penalty of not more than \$50,000 for each violation.

- OIG could also impose a civil money penalty upon each "responsible physician" of not more than \$50,000 for each violation. In addition, the OIG may exclude the physician from Medicare participation for up to five years. A responsible physician is a physician within the meaning of section 1861(r)(1) of the Act (doctor of medicine or osteopathy) who is employed by, or under contract with the hospital, who, in that capacity, had professional responsibility for the provision of examination or treatment for the individual, when the violation occurred. A physician may be employed by, or under contract with, a hospital even though the physician receives no compensation from the hospital for furnishing medical services.

For purposes of this provision, a physician would be considered under contract with the participating hospital, and therefore a responsible physician within the context of these regulations, if he or she has a written or oral agreement to take professional responsibility for providing examinations or treatment in the hospital's emergency room for individuals seeking emergency medical care, or for the proper transfer of these individuals whether or not the physician receives compensation from the hospital for providing the services.

In addition, if the provision of emergency medical services is shared by more than one responsible physician, each responsible physician could be held liable and a civil money penalty up to the maximum amount, as well as exclusion from the Medicare program for up to five years, could be imposed against each responsible physician for each violation.

We would revise §§ 1003.100, 1003.102, 1003.103 and 103.105 to reflect these provisions.

Determination of penalty amount.

We propose to establish in 42 CFR 1003.106 three specific criteria and one general criterion that we would consider in determining the penalty amount—

- The degree of culpability of the hospital and the responsible physicians.
- The seriousness of the individual's condition in seeking emergency medical services.

- The prior history of the hospital and the responsible physicians in failing to

provide appropriate emergency medical services or appropriate transfers.

- Other matters required by justice.

We specifically welcome comment on the application of these and other possible criteria, and on the inclusion of specific aggravating and mitigating factors, to be considered in levying penalties under this provision.

We believe that the authority to assess civil money penalties against the responsible physician as well as the hospital will be a strong incentive for both the physician and the hospital to respond to the medical needs of individuals with emergency medical conditions and women in active labor.

HCFA would refer appropriate cases for possible money penalties to the OIG, while at the same time HCFA will authorize the Medicare State survey agency to conduct a complaint investigation if warranted.

The OIG would have to prove by a preponderance of the evidence that the hospital or the responsible physician or physicians, or both, failed to provide emergency medical treatment as required by section 1867 of the Act. This provision would be in 42 CFR 1003.114.

The OIG would notify hospitals and responsible physicians assessed civil money penalties in accordance with 42 CFR 1003.109, which includes hospital and physician appeal rights. We would revise that section to require that the notice would include a description of the episode for which the penalty is proposed and why the penalty is being assessed.

We would also make necessary technical changes to §§ 1003.100, 1003.106, 1003.109 and 1003.114 and add to § 1003.101 definitions of "participating hospital" and "responsible physician", as discussed above.

v. Civil enforcement.

An individual who suffers personal harm, or a medical facility that suffers a financial loss, as a direct result of the hospital's violation of a requirement in 42 CFR 489.24, may bring a civil action, in an appropriate Federal district court, against the hospital for damages and other equitable relief as appropriate. No civil action may be brought more than two years after the date of the violation. The Federal district court will apply the law of the State in which the hospital is located. According to the Conference Committee Report, the committee included the language concerning other equitable relief as appropriate as a directive to the courts:

[T]he [House of Representatives] language allowing courts to grant 'other appropriate relief' was also modified to read 'other equitable relief as appropriate' to give the

courts clearer direction that such relief should be within the courts regular equitable powers and should be granted for the purpose of remedying the violation or deterring subsequent violations. (H.R. Rep. No. 453, 99th Cong., 1st Sess. 476 (1985).)

We do not believe it necessary or appropriate to revise the regulations to reflect this provision.

vi. Preemption of State law. The legislation provides that it does not preempt State or local law except where there is a conflict with the statutory provision. Since Federal law ordinarily supersedes State law where there is a conflict, it is not necessary to include this provision in regulations.

2. Responsibilities of Hospitals Receiving Improperly Transferred Individual.

Preliminary findings of study being conducted by the OIG have confirmed that a number of patients in unstable condition have been transferred improperly and that the cases have not been reported to HCFA. Because we need to know about *all* improper transfers, we are proposing to add a new paragraph (g) to § 489.20 to require a hospital that suspects it may have received an improperly transferred individual to report to HCFA and to the State survey agency. To be in compliance with this requirement, the receiving hospital would have to report any suspected incident within 72 hours of its occurrence. This requirement would appear in manual instructions.

We propose to include in § 489.24 a paragraph (f) that would require a hospital to report promptly patients it receives who were transferred in suspected violation of § 489.24(d).

We also propose to add a paragraph to § 489.53(a) to show that failure to report improper transfers may subject the receiving hospital to termination of its provider agreement.

In those instances in which HCFA determines that a hospital is in violation of § 489.20(g), we would initiate termination action.

3. State Survey Agency Responsibilities

The preliminary findings of the OIG study also identified incidents of improper transfer being reported to the State survey agency that were not then reported to HCFA.

To assure that we are aware of all instances of improper transfer, we also propose to require the State survey agencies to report promptly any credible complaints (that is, complaints that are specific and detailed enough to be investigated) related to violations of section 1867 of the Act. Therefore, we intend to revise § 405.1903.

Documentation of findings, by adding a new paragraph (d) that would require State survey agencies to inform HCFA of credible reports of violations of § 489.24.

IV. Regulatory Impact Statement

A. Introduction

Executive Order (E.O.) 12291 requires us to prepare and publish an initial regulatory impact analysis for any proposed regulation that meets one of the E.O., criteria for a "major rule"; that is, that would be likely to result in: an annual effect on the economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or, significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a proposed regulation would not have a significant economic impact on a substantial number of small entities. Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if this proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis also must conform to the provisions of section 603 of the RFA. For purposes of the RFA, we treat all providers as small entities.

B. Impact on CHAMPUS, CHAMPVA, and VA programs

This proposed rule would require hospitals to provide inpatient hospital services to individuals who have insurance coverage under CHAMPUS, CHAMPVA, and VA programs. Further, the CHAMPUS/CHAMPVA-determined allowable amount from these programs must be accepted as payment in full (less applicable deductible, patient cost-share and noncovered items). The effect of these two requirements is the result of the statute, not this proposed rule.

C. Impact on Hospitals

The provision requiring a Medicare participating hospital with an organized emergency department to provide emergency services within the capabilities of the hospital to any individual with an emergency medical condition and to any woman in active labor would ensure that everyone in an

emergency situation will be stabilized before discharge or transfer, or the hospital may be terminated or suspended from the Medicare program. This provision is also the result of the statute and not this proposed rule, and we have been actively enforcing the statutory requirements. Further, it should be noted that currently, under 42 CFR 124.600, et seq., of the Public Health Service (PHS) regulations, the nearly five thousand hospitals nationwide that received Hill Burton construction grants and loans are required to participate in the Medicare program if eligible to do so. Under these regulations, hospitals are required to provide emergency medical services to any person who resides (or, in the case of some hospitals, works) in the hospital's designated health service area.

We believe the great majority of hospitals do not inappropriately transfer or refuse to treat patients with limited ability to pay for services. The aggregate economic impact of this provision should be minimal, primarily affecting only those hospitals not already under a Hill-Burton agreement, those not complying with their agreements, or those hospitals that as a matter of policy have interpreted their obligations narrowly and refused services to individuals not specifically covered by the Hill-Burton requirements (i.e., those not living or working in the given hospital's designated health service area).

We also are proposing to require each hospital to retain a separate, signed acknowledgement from the beneficiary attesting to the receipt of the "Important Message from Medicare" and a copy of the "Message" itself. Although this would create a slight increase in hospital administrative costs, it is not expected to affect Medicare or Medicaid program expenditures significantly. Hospital cost increases would be limited to obtaining and retaining the beneficiary's acknowledgement. However, we believe that over the long run more informed patients should reduce the necessity to file complaints, off-setting any increased costs.

D. Impact on Patients

After the 1979 establishment of the above-mentioned Hill-Burton requirement, very few community service complaints have been filed with PHS' Office for Civil Rights, although numerous criticisms have been reported in the media concerning admissions for emergency services. We believe that establishment of an additional, broader requirement and an additional avenue of complaint may result in reporting of a larger number of incidents. However, in

view of the PHS experience we continue to anticipate that incidents will be sporadic and relatively isolated. We expect this provision basically to increase the incentives for hospitals to avoid such incidents thus improving emergency care for uninsured individuals.

E. Conclusion

For these reasons, we have determined that a regulatory impact analysis is not required. Further, we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities and would not have a significant impact on the operations of a substantial number of small rural hospitals. Therefore, we have not prepared a regulatory flexibility analysis.

V. Paperwork Reduction Act

Sections 405.1903, 489.20 and 489.27 of this proposed rule contain information collection requirements. As required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3504), we have submitted a copy of this proposed rule to the Executive Office of Management and Budget (EOMB) for its review of these requirements. Other organizations and individuals desiring to submit comments on the information collection requirements should follow the instructions in the **ADDRESS** section.

VI. Response to Comments

Because of the large number of comments we receive on proposed regulations, we cannot acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments received timely and respond to the major issues in the preamble to that rule.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 485

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare.

42 CFR Part 1001

Administrative practice and procedure, Fraud, Health facilities, Health professions, Medicare.

42 CFR Part 1003

Administrative practice and procedure, Archives and records, Grant programs—social programs, Maternal and child health, Medicaid, Medicare, Penalties.

Title 42 of the Code of Federal Regulations would be amended as follows:

A. Chapter IV is amended as follows:

1. Part 405, Subpart S is amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

a. The authority citation for Part 405, Subpart S is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395f, 1395x, 1395bb, 1395cc, 1395dd, 1395qq, 1395rr, and 1395tt.

b. Section 405.1903 is amended by adding a new paragraph (d) to read as follows:

§ 405.1903 Documentation of findings.

(d) If the State agency receives credible information (that is, information that is specific and detailed enough to be investigated) to the effect that a hospital has violated § 489.24 of this part, the State agency is to report the information to HCFA promptly.

2. Part 489 is amended as follows:

a. The authority citation for Part 489 is revised to read as follows:

Authority: Secs. 1102, 1861, 1864m, 1866, 1867, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa, 1395cc, 1395dd, and 1395hh), and sec. 602(k) of Pub. L. 98-21 (42 U.S.C. 1395ww note).

b. The table of contents is amended by adding §§ 489.24, 489.25, 489.26, and 489.27 to Subpart B to read as follows:

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

• • • • •

Subpart B—Essentials of Provider Agreements

Sec.

• • • • •

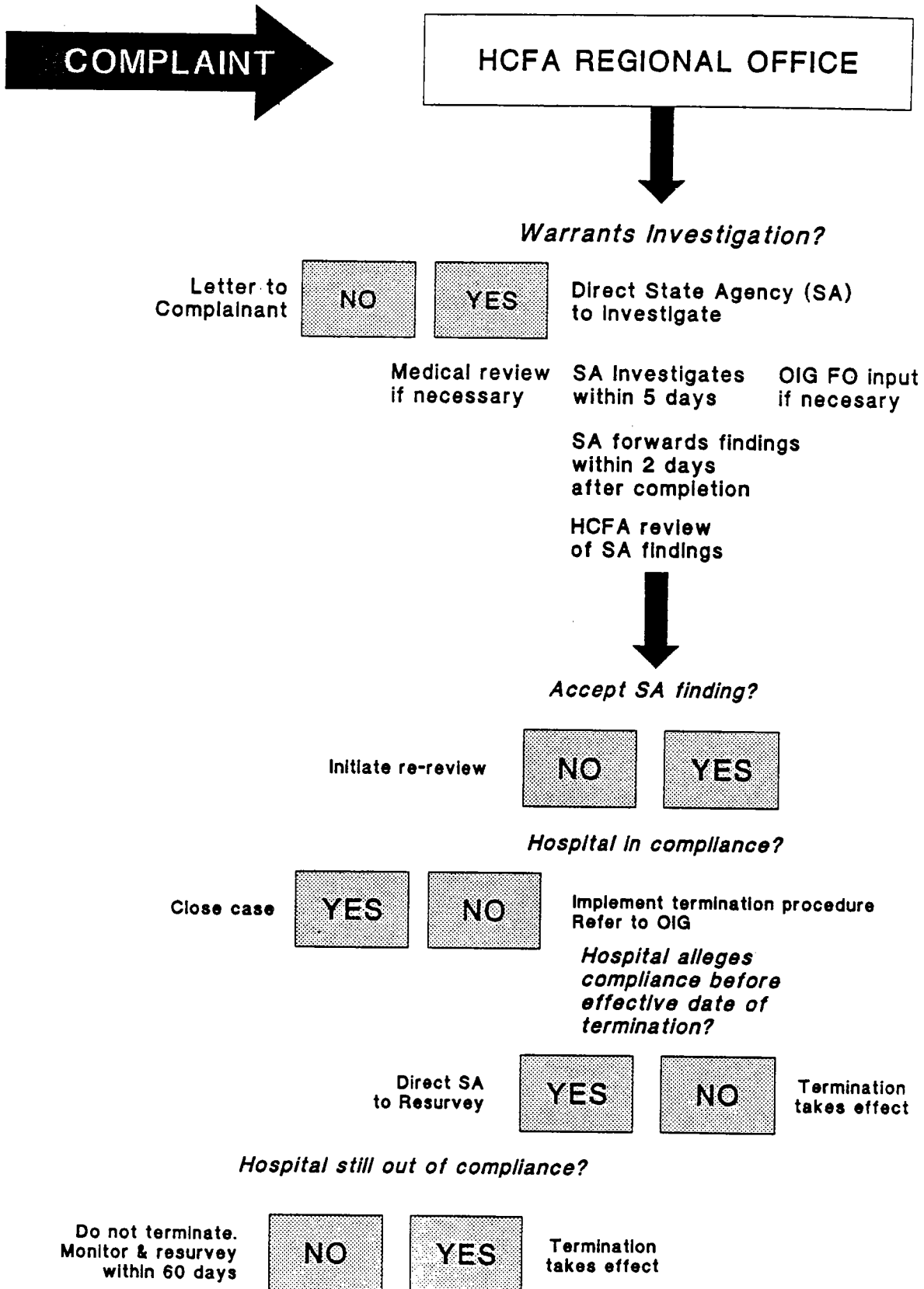
489.24 Special responsibilities of Medicare hospitals in emergency cases.
489.25 Special requirements concerning the CHAMPUS and CHAMPVA programs.
489.26 Special requirements concerning veterans.
289.27 Beneficiary statement of discharge rights.

c. In § 489.20, the introductory text is republished and the section is amended by adding paragraphs (f), (g), (h), (i), and

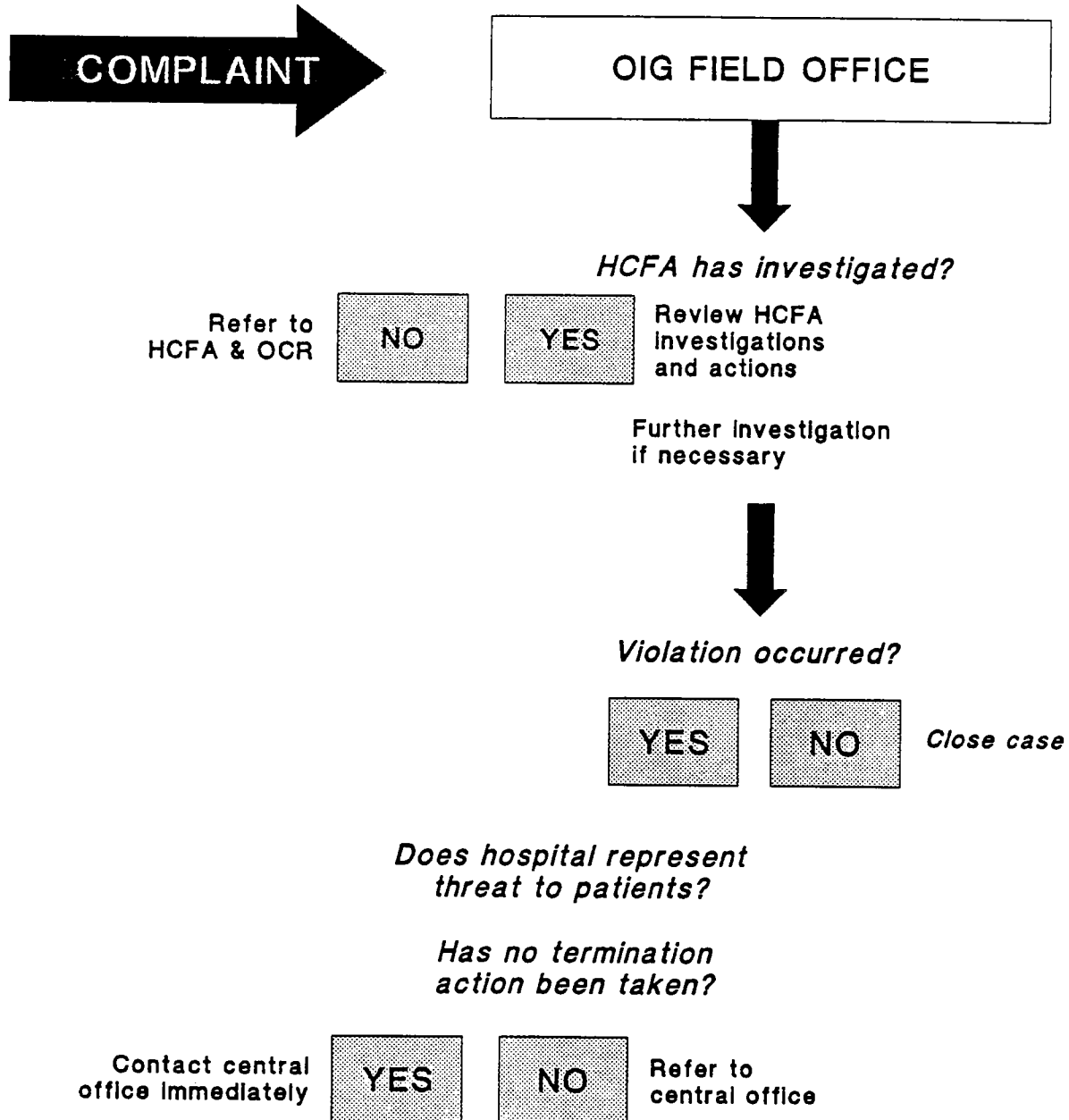
APPENDIX C

Steps In Procedures for Response to Complaints of Patient Dumping

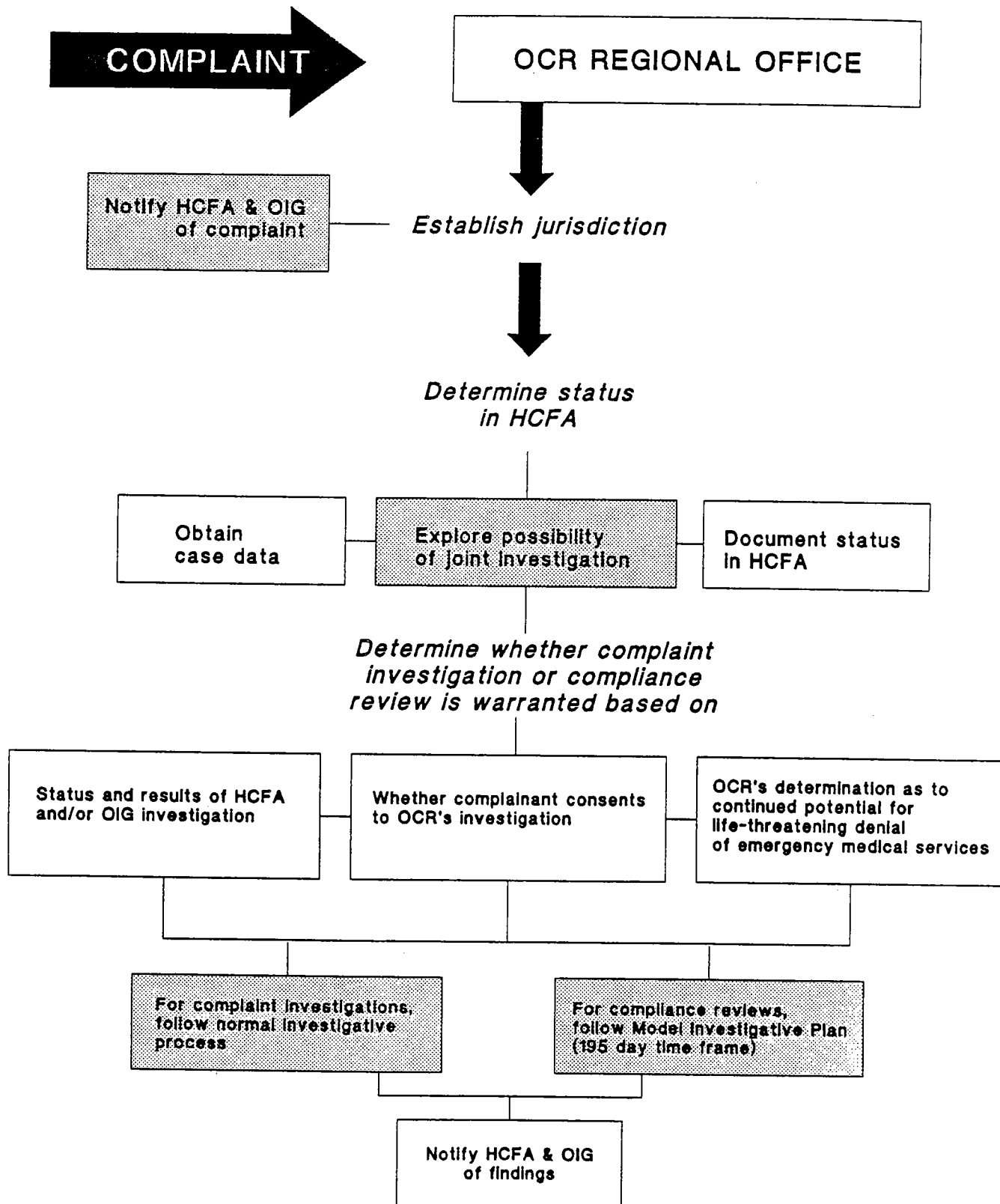
HCFA PROCEDURE FOR RESPONSE TO COMPLAINTS OF PATIENT DUMPING



OIG PROCEDURE FOR RESPONSE TO COMPLAINTS OF PATIENT DUMPING



OCR PROCEDURE FOR RESPONSE TO COMPLAINTS OF PATIENT DUMPING



APPENDIX D

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Abbott / P. I. ...
HCFA
Health Care Financing Administration
Denny
Manjiv / ...

OCT 19 1988

Memorandum

Date
From *W.L. Roper* William L. Roper, M.D.
Administrator *Jimmy Coleman*

Subject: OIG Draft Report: "Patient Dumping after COBRA: U.S. Department of Health and Human Services Response to Complaints," OAI-12-88-00831

To: The Inspector General
Office of the Secretary

We have reviewed the draft report entitled "Patient Dumping after COBRA" The report made four recommendations to the Department, Office of Civil Rights (OCR), and HCFA. The recommendations are designed to improve coordination and handling of complaints. We are in basic agreement with them. Our specific comments on each are attached for your consideration.

Thank you for the opportunity to comment on this report.

Attachment

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DIG	<input checked="" type="checkbox"/>
AIG-A	<input type="checkbox"/>
AIG-AI	<input checked="" type="checkbox"/>
AIG-I	<input type="checkbox"/>
ADM	<input checked="" type="checkbox"/>
OIG/IG	<input type="checkbox"/>
EX SEC	<input checked="" type="checkbox"/>
DATE SENT	<u>10/20</u>

RECEIVED
OFFICE OF THE INSPECTOR GENERAL
1988 OCT 20 AM 9:20

Comments of the Health Care Financing Administration
on the OIG Draft Report: "Patient Dumping after COBRA:
U.S. Department of Health and Human Services Response to
Complaints," OAI-12-88-00831

OIG Recommendations

The Department should seek to configure responsibilities of the components in order to provide a unified response to a single complaint, or series of complaints involving a single hospital, so as to improve response and the efficient resolution of complaints.

HCFA Comments

We currently notify OCR of forthcoming investigations. We will contact OCR and OIG to pursue the goal of coordinated investigations and whenever practical, combine investigative teams. OCR staff are currently welcome to accompany the State agency (SA) surveyors. Integration of HCFA and OCR activities, however, must not delay the investigation. SAs are required to investigate alleged dumping within 5 workdays of notification.

OIG Recommendations

HCFA and OCR should pursue a legislative initiative to align their authorities under Hill-Burton and COBRA and to establish a common departmental definition as to what constitutes patient dumping under the relevant provisions of those statutes.

HCFA Comments

We will meet with OCR to consider a legislative initiative to align our authorities under Hill-Burton and COBRA. OCR is currently responsible for violations of Hill-Burton which do not also violate COBRA (e.g., discrimination against certain types of patients in non-emergency situations). OCR should continue to be responsible for these types of cases; there is no rationale for HCFA involvement.

OIG Recommendations

In order to develop an efficient and consistent response to complaints, a set of guidelines should be developed by the Department which outlines in detail what actions can be taken (termination, suspension, civil money penalties, etc.) in response to varying levels of violations (isolated incident, pattern of abuse, evidence of willful negligence, etc.).

HCFA Comments

We initiate termination action if there is a single incident, not as a punitive action, but because our experience indicates that this usually results in swift correction of the problem. Our intent is to assure adequate care in a safe environment which this approach accomplishes. We will gladly participate in a cooperative effort to develop a common set of guidelines.

OIG Recommendation

A set of timeframes for investigation and resolution of complaints should be developed, and a screening mechanism (such as the SA) used to focus investigative resources on more productive cases.

HCFA Comments

HCFA has set deadlines for each step in the development of an investigation and uses the SA for immediate screening of allegations. We fully support this recommendation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

TELETYPE UNIT
10/10/88
M.D.
Shelton

Office of the Secretary

Washington, D.C. 20201

MEMORANDUM

DATE : October 5, 1988

FROM : Audrey F. Morton *Cherly S. Horton*
Director
Office for Civil Rights

SUBJECT: OCR Comments: OIG Draft Report: "Patient Dumping
After COBRA: U.S. Department of Health
and Human Services (HHS) Response to
Complaints," OAI-12-88-00831

TO : Richard P. Kusserow
Inspector General
Office of the Inspector General

The subject Office of Inspector General (OIG) draft report has been reviewed for comments as requested in your August 9, 1988, memorandum. Thank you for the opportunity to present the Office for Civil Rights' views on this report.

Your stated purpose for the inspection was to determine how the various components investigate and respond to complaints of patient dumping, the problems encountered, and the changes needed to correct any past difficulties. The report, which analyzed the HHS investigative procedures in patient dumping utilized by the Office for Civil Rights (OCR), the Health Care Financing Administration (HCFA), and the OIG, crystallizes some of the major problems confronting HHS staff involved in investigating complaints of patient dumping. We believe that the identification of these problems is a positive step in the Department's continuing effort to eliminate patient dumping. There are, however, a number of observations made in the Findings Section that we feel are inaccurate and indicate a need for further clarification. Our comments, as they apply to the various findings or recommendations presented in the draft report, are provided below.

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Statement of Finding:

Procedures for the investigation and referral of dumping complaints are relatively new or are still evolving.

Under this finding, the report discusses the "new OCR instructions" concerning dumping cases. While it is true that OCR issued additional guidance in April 1988 to its regional offices, OCR regional offices were not without written investigative procedures for use in conducting patient dumping investigations. Although the report repeatedly refers to the newness of OCR's instructions, this assessment is inaccurate. It does not reflect the fact that OCR has investigated dumping complaints under its existing investigative procedures since 1980. It should be noted that the primary work of OCR is to conduct complaint investigations and compliance reviews. Consequently, OCR has always had an Investigative Procedures Manual which the regional offices utilized to investigate complaints filed with this office under all of our authorities.

OCR began conducting compliance reviews of Hill-Burton assisted facilities and investigating all complaints filed under the community services regulation pursuant to a Memorandum of Understanding with the Health Resources Administration (HRA). Although HRA retained authority for the final disposition of complaints and post-investigative enforcement activities, OCR conducted the investigations. Patient dumping issues were a part of a significant number of those investigations. On December 8, 1980, OCR was delegated full responsibility for the community service program. In January and later in June 1981 OCR issued comprehensive manuals on Hill-Burton investigations and these manuals continue to be used by our investigative staff. Prior to the COBRA enactment, HCFA received many complaints involving patient dumping that were investigated by OCR, and in some instances HCFA had an active role in various stages of those investigations.

Statement of Finding:

OCR issued its only instructions to its regional offices in April 1988.

Again, the reference to the newness of OCR instructions is not accurate. The April 1988 OCR guidelines were issued in response to regional requests for more specific guidance on conducting compliance reviews. The priority status given to dumping cases was not a result of OCR's lack of instructions to regional offices or inexperience in investigating patient dumping issues. The recent priority attached to patient dumping cases is a direct result of the recent number of HCFA/OIG referrals to OCR and the need to coordinate with OIG and HCFA regarding reporting procedures and to ensure accuracy in reporting.

As stated previously, procedures for investigating patient dumping cases have been in place since 1981. Historically, these cases have been investigated not only under the Hill-Burton authority, but also under Title VI of the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973 when appropriate. The recent issuance of guidelines for handling patient dumping matters was an effort to refine and enhance procedures for investigations of patient dumping complaints and compliance reviews. OCR's April 1988 guidelines provide for consistency in approaching the issue of patient dumping and uniformity on a national level in attaching the same priority to these cases. As a result, the April guidelines provide more extensive guidance for compliance reviews while providing only refined guidance in handling complaints. You will note that the guidance provided on complaints primarily focuses on the in-take processing of referrals/receipts and reporting requirements. Complaint investigation activity continues to be based on OCR's existing Investigative Procedures Manual as well as the Hill-Burton guidelines provided during 1980 and 1981.

Under this same finding, the comment was reported on page 8 from one regional office that "...OCR ... relied solely on HCFA's investigation to determine if a case has merit because it lacks the necessary medical expertise." This statement is not accurate.

OCR regional offices have routinely used medical experts from numerous sources, particularly in investigating AIDS, and other Section 504 complaints, as well as in prior investigations of "Baby Doe" complaints. Our instructions to regional offices to obtain HCFA case files prior to initiating OCR investigations is illustrative of our efforts to avoid duplicating efforts and unnecessarily burdening the recipients. This practice has nothing to do with OCR's lack of access to medical experts.

In addition, staff comments on page 8 regarding reliance on HCFA investigations because of HCFA's better enforcement authority are vague. To clarify, we note that there are instances where complaints have been closed because OCR determines that HCFA has obtained the same remedies that OCR would have pursued. This, again, is an effort to avoid duplicating efforts and unnecessarily burdening the recipients. It also should be noted that a number of complaints have been closed with the instructions that future compliance reviews be opened. For example, in one of the regional offices subject to your inspection, nine (9) complaint referrals from HCFA were closed as complaints and opened as compliance reviews, and ten (10) complaints were closed because HCFA obtained remedies that OCR would have pursued. The process of converting complaints into compliance reviews ensures that questionable practices regarding the recipient's obligation to treat patients, emergent or otherwise, are investigated by OCR through its compliance review process.

The statement on page 8,

"In addition, those instructions detail how a dumping complaint should be investigated and indicate that a full on-site investigation should be conducted. The information to be gathered by the OCR investigator, according to the Model Investigative Plan includes:..."

is not accurate. The April guidelines do not provide details for investigating a complaint. The guidelines instruct on processing complaints, i.e., attaching priority; assigning a special case docket number; using specific case information management system codes; and determining the appropriateness of a compliance review.

The guidelines refer staff to standard OCR procedures when investigating a complaint. The model investigative plan referred to is the plan for compliance reviews; there is no investigative plan for complaints included in the April guidelines.

Statement of Finding:

There are different conceptions within the Department as to what constitutes patient dumping. For example, OCR's instructions indicate that an additional set of authorities may be brought to bear on hospitals that engage in patient dumping. (page 9)

OCR is aware that COBRA covers circumstances in which a patient is denied needed emergency services on a basis other than an economic factor since COBRA requires screening of all patients and treatment of all patients in need. However, the existence of additional authorities enforced by OCR makes it mandatory that we investigate patient dumping cases under them when the complainant alleges discrimination on a basis prohibited by a specific law. We believe that the enactment of Section 9121 of COBRA was not intended to diminish the enforcement tools available under other authorities, but to broaden the enforcement mechanisms to fit the newly identified instances and bases of discrimination related to economic factors and termed as "patient dumping." We also believe that the inference that patient dumping can only occur where COBRA applies is not supportable. We believe that Congress was aware that other legislation existed to cover this issue on bases other than economics. Where patterns exist that show individuals are being denied appropriate emergency treatment based on factors other than those of economics, we believe that what is defined as patient dumping is practiced. Where a complaint does not involve a Hill-Burton facility, and the complaint alleges a patient dumping act on the basis of race, handicap, etc., OCR will investigate the issue whether the act is termed patient dumping or not. For the sake of consistency in our approach to this investigatory issue, we are convinced the application of the term patient dumping is appropriate. As our procedures require, such a complaint will be referred to OIG and HCFA because COBRA may apply as well.

OCR must investigate under the appropriate authority. In so doing, the definition of patient dumping is not expanded to issues beyond that which COBRA intends. Some of OCR's investigations may focus on more than financial considerations by virtue of the complaint allegation, but we do not believe this poses a problem in the handling of patient dumping complaints. In fact, the existence of the additional authorities broadens the spectrum of instances and bases where patient dumping may be identified. Recent studies indicate that there is a growing pattern of minority males being "dumped" in disproportionate numbers from emergency rooms.¹ In these cases, Title VI, Hill-Burton and COBRA may apply. The remedies available under these authorities together can have a much greater impact on this group of beneficiaries than the remedies available for the limited incident of denial of emergency services to an individual, as would be the case under Hill-Burton and possibly COBRA.

It is stated on page 9, "We did not find any evidence in the three regions we visited that a complaint of emergent patient dumping has been pursued under these authorities." The fact that the regional offices visited were not regional offices that have investigated patient dumping issues under other authorities should not be interpreted as an indication there is a different definition being applied, or that such investigations have not been conducted. OCR's conception of patient dumping issues has nothing to do with the authority under which the investigation will be conducted. Whether a case is classified as patient dumping depends entirely on the circumstances described in the allegation and whether the allegation meets the standard definitions currently defined as patient dumping by OCR, HCFA, and the OIG.

The existence of additional authorities within OCR that may apply to patient dumping should not be viewed as tools available to be brought to bear unjustifiably on hospitals. For example, in an attempt to avoid duplicative investigations by agencies within the Department, regardless of the authority involved,

¹ Patient Transfers: Medical Practice as Social Triage, David U. Himmelstein, MD, Steffie Woolhandler, MD, MPH, Martha Harnly, MPH, Michael B. Bader, MD, MPH, Ralph Silber, MPH, Howard D. Backer, MD, and Alice A. Jones, MD. AJPH May 1984, Vol. 74, No. 5.

OCR guidelines instruct our regional offices to review HCFA cases prior to initiating investigations. When it is clear that the violation has been remedied and the remedy is what OCR would seek, then a duplicate investigation will not be initiated under any authority. However, where a complaint alleges discrimination on the basis of that which is not covered in the HCFA investigation, OCR investigates, considering the data gathered by HCFA, to avoid duplicating HCFA's efforts and to ensure that all alleged patient dumping actions are properly investigated, whether under Hill-Burton or other authorities.

This process cannot be circumvented by the notion that a definition of patient dumping has any effect on the authority under which OCR investigates--the authority is dictated by the allegations of the complaint.

Statement of Finding:

"OCR's dumping procedures do not include instructions to the regional offices on how to approach non-emergency patient dumping,...." (page 9)

This omission exists so that the definition is not expanded to non-emergent patient dumping instances since such cases continue to be included in our routine case loads. Policies and procedures already exist to cover the handling of these investigations. We are unable to see the benefit to such a reference in this report.

Statement of Finding:

The OCR often lacks jurisdiction and has not yet taken enforcement action on dumping referrals from HCFA in the three regions studied. (page 14)

Eleven complaints are referred to as "pending" in OCR. A more accurate statement would be that eleven complaints have investigations in progress. This would be consistent with the term used in Exhibit 2 describing the stages of HCFA and OIG investigations.

Also, this comment implies that no changes have resulted from OCR's investigations, and this is not the case. OCR's procedures reflect our obligation to seek voluntary compliance whenever possible. The mode of voluntary compliance is a method widely endorsed by the current administration to remedy violations.

OCR has found this method to be very effective and successful in OCR negotiations with recipients. For example, during the period of your inspection, in one of the regional offices there were two patient dumping complaints closed with corrective actions secured. This section of the report should be revised to reflect the full range of OCR investigative activities.

RECOMMENDATIONS:

The Department should seek to configure responsibilities of the components in order to provide a unified response to a single complaint, or series of complaints involving a single hospital, so as to improve response and the efficient resolution of complaints. (pages 18 and 19)

OCR agrees that a unified approach to respond to patient dumping allegations will improve the response and efficient resolution of complaints. We look forward to working with other components to accomplish strengthening the Department's enforcement efforts in this vital area. We continue to support joint investigations where feasible. As you noted, in our guidance on patient dumping to the regional offices, we recommended that OCR staff coordinate investigative activities with HCFA when possible. However, we do not agree that OCR should delegate its responsibility for investigating patient dumping complaints under Hill-Burton to HCFA.

While it is true that COBRA has a more detailed statutory base and enforcement is stronger under that authority, we do not believe the enactment of COBRA was intended to diminished the enforcement tools available under other authorities. Both the community service assurance and civil rights laws are intended to ensure equal opportunity to all programs or activities funded by the Department.

OCR has had considerable experience in dealing with patient dumping issues. Patient dumping issues are a part of our overall Hill-Burton authority and are closely interrelated to other nondiscrimination laws that are enforced by OCR. The unified approach recommended to respond to one or more complaints filed against a single hospital will not necessarily be enhanced by a potential splintering of OCR's authority. Many cases that have Hill-Burton aspects also are filed under Section 504 or Title VI. The converse is also true.

We believe that the pursuit of defined coordination between components is the best approach, and one that will be equally beneficial to all concerned. It will ensure the desired improved response and the efficient resolution of complaints.

RECOMMENDATION:

The HCFA and OCR should pursue a legislative initiative to align their authorities under Hill-Burton and COBRA and to establish a common departmental definition as to what constitutes patient dumping under the relevant provisions of those statutes. (page 18)

The report contains examples on page 18 used to reflect the need to align authorities under Hill-Burton and COBRA, and to reflect the lack of conformity in a common definition of emergent patient dumping. OCR does not consider the examples used reflective of problems in the respective areas. For instance, a comment included in the report states:

"For example, lack of medical certification attesting that the benefits outweigh the risks for transfer of an unstable patient is a violation of COBRA, but not of Hill-Burton. This lack of conformity only diminishes the Department's enforcement authority in this area."

We note that while Hill-Burton does not require that a physician sign a certification before a hospital may transfer a person who has an emergency medical condition that has not been stabilized or who is in active labor, the regulation does contain equally effective requirements to ensure that patients are not arbitrarily transferred or discharged in an unstable

condition. Hill-Burton emergency provisions require that appropriate medical personnel determine that discharges or transfers will not subject the person to substantial risk of deterioration in medical condition. There is no analysis or evidence presented to illustrate how the differences in the requirements of COBRA and Hill-Burton diminish the Department's enforcement authority in this area. With OCR retaining authority to investigate complaints under Hill-Burton, the Department has additional assurance that patient dumping complaints that include allegations which cannot be reached under COBRA may be reached by OCR under Hill-Burton or additional authorities enforced by OCR. Such would be the case for complaints against children's hospitals that do not receive Medicare funds for kidney dialysis, "non-hospitals" that provide emergency services, and other facilities that are not Medicare participants that provide emergency services.

Again, the report, on page 18, refers to patient dumping in a non-emergent setting. The report indicates:

"As noted earlier, OCR has authority under Hill-Burton over patient dumping in a non-emergent setting. The authority of OCR in this area does not overlap with HCFA's authority under COBRA and this type of violation should not be included in the common definition of emergent patient dumping. Further, if OCR wishes to bring a discrimination action under Title VI or Section 504 for actions that may or may not involve emergent patient dumping, it may do so on its own accord, outside the Hill-Burton/COBRA framework."

The statement appears to suggest that OCR has expanded its definition of patient dumping. If this is the intent of the comment, then accompanying evidence included in the report would be beneficial to support such a position. OCR's definition of patient dumping includes situations in which a hospital that has the required service treats an emergent patient, and instead of admitting the person as an inpatient, either transfers the patient to another hospital for admission as an inpatient or discharges a patient that should have been admitted as an inpatient on a ground that is prohibited by law. Our investigative experience has shown that too often these patients are still in an emergent state, that most are discharged or transferred based on race, national origin, or the inability to pay

for services, and that many such instances have resulted in the death of individuals. This is a blatant form of patient dumping that certainly the Department would not wish to consider removing from the realm of patient dumping in a revised definition. We do not see that any problems are identified in this section which result from the present alignment of authorities under Hill-Burton and COBRA, or from the "lack of conformity in a common definition" of emergent patient dumping set forth in the examples.

RECOMMENDATION:

A set of timeframes for investigation and resolution of complaints should be developed, and a screening mechanism (such as the State agency) used to focus investigative resources on more productive cases.
(page 19)

This section references OCR investigative timeframes as "newly in place in OCR." This is inaccurate. These investigative timeframes have been in place in OCR since May 1980 when the Department became the Department of Health and Human Services. This discrepancy should be corrected.

As the final report is prepared, I hope that consideration will be given to the OCR comments provided herein. We look forward to discussions with HCFA and OIG to consider the merits of acceptance or rejection of the recommendations contained in the OIG report. We agree that the development of an efficient and consistent response to complaints, and that the development of Departmental guidelines are required to ensure that consistent actions are taken in regard to substantiated cases.

Again, thank you for the opportunity to provide our comments. If there are questions, please have your staff contact Patricia L. Mackey at 245-6118.