E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

30-Jun-1995 07:30pm

TO: (See Below)

FROM: Allison H. Eydt
Office of Mgmt and Budget, OIRA

SUBJECT: More Discussion Regarding Stark Volume Threshholds

As discussed in my E-mail dated 6/26, data we have received from HCFA relects breaks in laboratory distributions at 2,000 and 10,000 tests. Unfortunately, this data is unvalidated, self reported, and unrepresentative. It is difficult to imagine, however, that a 2,000 test ceiling in a shared office lab exception would result in substantial program abuse. Based on HCFA's "sample" of "shared office laboratories," 41% of these laboratories perform 2,000 tests or less per year and therefore, would receive relief from such an exception. It should be noted, however, that although 41% of all such labs sounds respectable for an exception, it may not be large enough politically. A 10,000 test ceiling would provide relief to an additional 38% laboratories (for a total 79%.)

Because a 10,000 test ceiling could result in program abuse, I asked HCFA to provide a continuous distribution of labs performing between 2,000 and 10,000 tests. HCFA explained that this analysis would take two to three weeks. I asked them to initiate it. Now they have come back and refused to pursue such an analysis. Unless we can motivate HCFA to comply with this request soon, it appears that we would have to create an exception based on the scant existing data. Under these circumstances, I recommend a conservative 2,000 test ceiling.

Other approaches to an exception could be incorporation of HCFA's legislative proposal into the rule (as discussed in my previous E-mail) or a rough translation of the 5 physician limit in this exception to a volume ceiling of perhaps 5,000 tests or so. It seems more rational to simply accept HCFA's physician limit, however, than to make another arbitrary leap to a comparable volume that is based on no data.

My preferred recommendation from all of the above would be straight adoption of HCFA's legislative proposal as an administrative exception. While possibly more flexible than a 2,000 test ceiling, it could result in less abuse than a 10,000 test ceiling. Most important, this proposal includes language

that prohibits a direct relationship between the test referrals of each shared office physician and his or her profits. This language is critical to discouraging program abuse.

RMO staff prefer no exception over all of the above because these proposals have questionable empirical bases.

In a previous E-mail, I informed you where I will be the next few days. Do not hesitate to contact me, if you want to discuss these issues further.

Distribution:

TO: Sally Katzen

CC: James B. MacRae Jr.
CC: John F. Morrall, III
CC: Jennifer L. Klein
CC: Mary W. Poag
CC: Daniel J. Chenok
CC: Joseph F. Lackey, Jr.
CC: Mark E. Miller
CC: John M. Richardson
CC: Timothy B. Hill
CC: Phyllis E. Kaiser-Dark
CC: Lisa M. Jones

DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR PLANNING AND EVALUATION
OFFICE OF HEALTH POLICY

PHONE: (202) 690-6870 FAX: (202) 401-7321

Date:

From: GREENBERG **To:** JENNIFER KLIME

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(202) 690-6870
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Phone: 456-2529
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Number of Pages (Including Cover): 1+9

Comments:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

HCF-342

Washington, D.C. 20201

FE 1995

TO: Claudia Cooley
Executive Secretary

FROM: Assistant Secretary for
Planning and Evaluation

SUBJECT: FINAL WITH COMMENT - Physician Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services (HCF-342) -- **NONCONCURRENCE**

Section 1877 of the Social Security Act prohibits certain physician referrals to "designated health services." The prohibited referrals are those which are believed to be primarily related to increasing the income of the referring physician, rather than diagnosis or treatment of a Medicare beneficiary. This regulation proposes to implement the portion of the law that applies to clinical laboratory services (Stark I). HCFA notes that another rule will be developed to implement the remainder of the statute dealing with the rest of the designated health services: physical and occupational therapy services, radiation therapy services, home health services, etc. (Stark II).

This is an issue which, as you know, is being considered for legislative modification in a different venue. Therefore, I recommend that this regulation be held in the Department until those discussions are concluded. However, in order to retain the option of issuing the regulation, I recommend that redrafting begin along the lines below.

If the decision is made to proceed with this regulation, I nonconcur with the publication of this rule as it is currently drafted. The statute itself exempts the great majority of the approximately 100,000 physician office laboratories that do business with Medicare (all solo practices and many group practices). HCFA proposes to exempt most of the remainder through an exception allowing physicians to perform tests on their own patients on the shared equipment. The preamble, however, reads as if we were rejecting almost all suggestions for exemptions. Both the memorandum to the Secretary and the preamble should be redrafted to change the tone and to emphasize our responsiveness to physician concerns. Finally, we should make clear that the Congress gave the Secretary explicit authority to create reasonable exemptions. We should willingly use this authority to minimize burden on small physician offices who seek practice cost efficiency through shared laboratory arrangements. A substantial rewrite will be needed to the preamble to make its tone positive.

The HCFA regulation should also be redrafted to eliminate any remaining impact on physicians who share office laboratory equipment as a matter of convenience to their own patients. HCFA does not provide an estimate of the number of shared physician office laboratories that would not meet the new in-office ancillary exemption as drafted; but I believe it to be small (HCFA should provide an estimate). Although I believe the in-office ancillary exception would exempt most legitimate shared laboratories, the approach in the regulation is cumbersome and the fact that most small shared laboratories would be exempt is not immediately clear.

A more straightforward approach to obtaining the desired result would be to exempt all shared laboratories which meet certain explicit criteria which minimize the potential gains from induced referrals. I suggest that the redrafted rule include both of the following exemptions (in order to assure that no benign situations are inadvertently rendered illegal):

1) shared physician laboratories that conduct fewer than 10,000 tests a year or $50,000 in dollar volume. (On the grounds that if total laboratory volume is low there is no substantial financial gain from induced referrals. I am not sure the numbers are right but they illustrate the principle.); or

2) any laboratory that is owned by 10 or fewer physicians if 90% or more of its volume is from these physicians' own practices (likewise, the potential for waste from induced referrals is minimal, and irrelevant legal strictures on groups are eliminated).

Moreover, I suggest that we consider an across-the-board de minimis dollar or volume exemption for all categories of covered services, such as ultrasound in gynecologist offices, orthopedic equipment in orthopedic offices, x-rays in any office, etc. This rule, if issued, could signal our intentions in this regard.

Finally, the way the in-office ancillary exemption is currently drafted could lead to enforcement problems and, in the extreme, some absurd results. The "direct supervision' requirement means that if a physician is called out of the office building on an emergency call, the laboratory technician in the shared laboratory must be notified and stop doing tests on that physician's patients. This is a burdensome result and we should not be issuing regulations that lead to non-compliance. The "direct supervision" requirement should be more flexible and should only require that the physician is ordinarily on-site. CLIA rules do not require that the technical supervisor or lab director be on-site. Furthermore, Congressional intent appears to allow off-site supervision. This change should be made regardless of any other changes.

Redrafting the regulation so an explicit exemption exists for shared physician laboratories according to several of the criteria above also has the advantage that the playing field would be leveled between group-practice laboratories and shared laboratories between solo practitioners. Therefore, I strongly urge this course.

David T. Ellwood

Prepared by: C. Colladay, 690-7770 and G. Greenberg 690-7794

cc: Anna Boyd

Comments In Favor of a Shared Laboratory Exception Made by Associations, Other Physician Groups, and Law Firms

American Society of Internal Medicine

- There should be a shared laboratory exception under which physicians can continue to provide lab testing to their patients, without any risk or program or patient abuse.
- The shared lab arrangement should include only a limited number of physician practices.
- The physician practices involved in the shared arrangement must occupy the same office space or their offices should be contiguous to one another.
- Each physician involved in the arrangement must only perform testing on his or her own Medicare patients.
- Each physician's employee must perform the test and the physician must supervise the performance of the test or the physician must perform the test for his or her Medicare patients. If a physician involved in a shared lab arrangement is sharing a laboratory employee with other physicians, the physician would need to supervise the employee when testing is being performed on his or her patients.
- Physicians involved in a shared laboratory arrangement should not be required to maintain a certain volume of referrals.
- Physicians involved in shared laboratory arrangements could be required to attest in writing that they meet these five criteria.

American Group Practice Association

- The final rule should recognize shared service arrangements between group practices and hospitals under circumstances that satisfy the spirit of the law and are consistent with the conditions set forth in other exceptions relating to compensation arrangements.
- All the compensation arrangements should be for identifiable services; the amount of the remuneration should be consistent with fair market value, and should not be determined by the volume or value of referrals; and the remuneration arrangements should be commercially reasonable even if no referrals were made.

  (Note: The OBRA '93 amendments contain a number of compensation arrangement exceptions that accommodate this recommendation.)

Association of American Medical Colleges and the Medical Group Management Association (same comments)

- HCFA should provide an exception to allow shared laboratory arrangements between faculty practice plans and hospitals that meet the following criteria.
  - The shared laboratory facility, the faculty practice plan and affiliated hospital (or other entity) are part of the same medical complex.
  - The costs of operating the shared facility are shared on the basis of utilization by each party, so that each party pays only its own costs and does not subsidize the provision of laboratory services to the other.
  - The creation or continuation of the shared facility arrangement is not related to the volume or value of referrals of patients between the clinic and hospital (or other entity) for other, non-Medicare services.

American Academy of Neurology

- There should be a shared laboratory exception if the following conditions are met:
  - The shared laboratory arrangement involves a limited number of practices.
  - The physicians involved in the shared arrangement occupy the same office space or their offices are contiguous.
  - Each physician involved in the arrangement is only performing testing on his or her own patients.
  - The physicians involved in the arrangement do not have to maintain a certain volume of referrals.

American Association of Clinical Endocrinologists

- The shared laboratory arrangement involves a limited number of practices.
- The physicians involved in the shared arrangement occupy the same office space or their offices are within the same building.
- Each physician involved in the arrangement is only performing testing on his or her own patients.
- The physician is actually performing the testing on his or her own patients or supervising his or her employees who perform the testing.

- The physicians involved in the arrangement do not have to maintain a certain volume of referrals.

American College of Rheumatology

- The shared laboratory arrangement involves a limited number of practices.
- The physicians involved in the shared arrangement occupy the same office space or their offices are contiguous.
- Each physician involved in the arrangement performs testing on his or her own patients.
- The physicians involved in the arrangement do not have to maintain a certain volume of referrals.

American Medical Association

- All physicians "sharing" the laboratory have office space in the same building or complex where the laboratory is located.
- All laboratory testing is performed on site.
- The laboratory is not a separate corporate entity.
- All physicians "sharing" the laboratory actively supervise the testing performed by the laboratory.
- The laboratory provides services only for patients of the physicians "sharing" the laboratory.
- All laboratory tests are billed by the ordering physician under that physician's provider number.

The American Academy of Family Physicians

- The shared laboratory is owned by two or more physicians not in a group practice for the exclusive use of these physicians in performing clinical laboratory testing only for their patients.
- Each physician owner of a "shared lab" should bill individually for the laboratory services he or she personally orders from the lab.
- The shared lab should be located in the same building in which the laboratory owners practice or in a geographic site remote from one or more of the owners practices; that is, in a site central to the owners' various practice locations.

The Law Offices of Foley and Lardner

- The shared lab services should be performed by a physician member or employee of a group that has entered into an arrangement with one or more other physicians or group practices for the operation of a clinical laboratory.
- The location requirements should be the same as for the in-office ancillary services exception; that is, in the same building as the physicians practice.
- Billing should be limited to the physicians or group practices that have entered into the arrangement for the operation of a clinical laboratory.
- The operation of the laboratory should be a joint responsibility of participating physicians and or practice groups with actual costs shared on per test basis. Shared labs would be required to demonstrate that they simply passed actual costs through to the participating physicians and group practices with no accumulation or distribution of net earnings. (This requirement will ensure that this exception will not permit physician joint venture labs.)

Medical Oncology Association of Southern California, Inc.

- The shared lab is staffed only by the physicians' own employees.
- The services are provided to the physicians' established patients only.
- The laboratory fulfills all requirements established for an exception to the self-referral prohibitions that apply to a group practice, except that a formal group association is not required.

The Law Offices of McDermott and Traynor

- The services are furnished personally by the referring physician, a member of the referring physician's association of physicians, or a non-physician employee of the referring physician or the association who is personally supervised by the referring physician or another member of the association.
- No separate legal entity is established to operate the laboratory, but rather each physician provides laboratory services to his or her own patients through his or her office practice.
- The laboratory performs tests only for the patients of the participating physicians.
- The physicians share only laboratory equipment.

- Each physician is the provider of the laboratory services, and each physician bills the Medicare program for the laboratory tests performed for his or her patients, and is reimbursed according to Medicare's laboratory fee schedule. (Because there would be no additional billing, there would be no potential for Medicare abuse or excess Medicare costs.)

- No profits are generated by the laboratory or shared by the physicians.

- An expense-sharing arrangement among physicians in the same building greatly increases patient convenience, as patients are not required to travel to another location for necessary laboratory tests.

Salem Medical Group

(Salem Medical Laboratory, Ltd., is a subchapter-S corporation wholly owned by a group of 23 physicians who practice in and around Salem, Massachusetts. They purchased a laboratory 6 years ago. They believe it is possible to structure an exception for shared laboratories which will permit physicians to function effectively, while not providing a loophole for abusive arrangements.

- Require that all owners of the laboratory be physicians, so that an outside laboratory operator cannot, under the guise of a "shared laboratory" come into a community and generate business by selling investment interests to physicians.

- Require that every physician own an equal share in the business, so that higher volume physicians cannot be rewarded by larger investment interests. (Note: lower volume physicians will be disproportionately rewarded under this plan).

- Require that no more than a limited proportion of the tests be performed by a reference laboratory, to assure that the shared laboratory really functions as a full-service laboratory for the convenience of the physician-investor.

Valley Hematology - Oncology Medical Group, Inc.

- A Board Certified Hematologist/Oncologist, shares an office suite with another hematologist/oncologist. They have independent practices but share an in-office laboratory devoted solely to providing their patients with needed services such as immediate evaluation of their blood counts in a detailed manner and automated chemical profile testing. The final rule should allow this laboratory ownership to continue.

Marshfield Clinic

- Exception should apply to laboratory facilities shared by a single hospital and a single group practice where the parties divide expenses on a basis that reasonably approximates the costs associated with the tests performed for each party's patients and where each party bills for and retains revenue associated with the testing of its own patient.

[Attachments that concern CLIA laboratories directly follow.]

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

29-Jun-1995 07:52pm

TO: (See Below)

FROM: Allison H. Eydt
Office of Mgmt and Budget, OIRA

SUBJECT: Brief Follow-up on Tuesday's Meeting

Jen Klein informs me that the main outstanding issue remains Stark. Before I leave for Chicago, I will send two more E-mails on this.

Mary P. mentioned the following items:

. Draft 10 pager for roll-out -- HCFA should be faxing this by C.O.B. tomorrow and I have asked Phyllis to look for it. I will come in tomorrow to review it. It is my understanding that CLIA items tentatively will be included. I will pay special attention to them. As mentioned before, they may not be worthy;

. HCFA assertions that Stark I does not conflict with CLIA -- Mary tells me that you brought this up, and HCFA denied that problems exist. I have contacted HCFA and requested a conference call to get the facts. As far as I know, however, the conflicts do exist; Medicare does not pay for services provided under the auspices of certain flexible CLIA provisions, e.g. microscopy. As soon as we suspected this, I asked the Department to investigate an exception from direct supervision requirements for such CLIA labs. I asked the Department to consider it from policy, budgetary, and legal perspectives. They have not responded. . . ;

. HCFA's CLIA "black box" proposal -- This regulatory proposal has merit, but it doesn't go far enough. HCFA should be amending CLIA statute to exempt "black box" technologies entirely from CLIA oversight. It is possible that this approach could compete with the Archer bill exempting all physician labs; and

. Must HMO regulatory reforms be legislated? -- Yes, most meaningful reform would require statutory amendment. In particular, I asked that HCFA consider the elimination of the entire Federally Qualified HMO program which subsidizes and regulates private pay HMOs. Elimination of this program would result in noticeable legislative and regulatory deletions.

Distribution:

TO: Sally Katzen

CC: Phyllis E. Kaiser-Dark
CC: James B. MacRae Jr.
CC: John F. Morrall, III
CC: Daniel J. Chenok
CC: Joseph F. Lackey, Jr.
CC: Mary W. Poag
CC: Jennifer L. Klein

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

30-Jun-1995 08:59pm

TO: (See Below)

FROM: Allison H. Eydt
Office of Mgmt and Budget, OIRA

SUBJECT: Comments on Reinventing HCFA Regulations

In general, I remain dissatisfied with HCFA's performance in this exercise. Overall, they resist pursuit of dramatic reforms that would require statutory amendment. Because many of the most burdensome requirements in HCFA's rules originate in statute, this approach makes it extremely difficult for HCFA to compete with more aggressive policies in Congress. Where administrative discretion does exist, i.e. personnel standards, HCFA fails to do more than "pilot" their elimination. Also, although some of HCFA's initiatives look good on paper, HCFA may fail to implement them in "good faith" (e.g. nursing home enforcement?)

My comments on HCFA's roll-out paper:

. Nursing Home Enforcement (p. 6) - In this entry, HCFA promises future amendments to participation rules and describes the published enforcement rule. First, it is important that HCFA announces a meaningful time frame this Administration for improving the participation rules. Second, unless HCFA can demonstrate otherwise, the nursing home industry will have difficulty believing that HCFA will make meaningful reforms to the participation rules in the absence of statutory amendment (and HCFA doesn't commit to this.) Third, HCFA's discussion of the enforcement rules does not highlight its innovative enforcement category entitled "substantial compliance." In simple terms, HCFA should explain how this new enforcement scheme provides flexibility to the industry by focusing enforcement on quality of care deficiencies, rather than on process. Fourth, HCFA should be able to say good things about the enforcement rule's public reception. If recent publicity has not been favorable, HCFA should consider dropping this initiative entirely.

. Physician Attestation (p. 7) - Why isn't HCFA mentioning the first attestation initiative which eliminated annual certifications by physicians? This policy already has been published . . . Second, OIRA is committed to assisting HCFA in expeditiously publishing rules eliminating claim by claim attestations. Why can't HCFA promise to finish this initiative

this summer? Couldn't HCFA publish a final rule without a prior proposal?

. CLIA proposals (pp. 8-10) - Overall, although these proposals have merit, they do not provide the same degree of flexibility as entire exemptions from CLIA oversight. For example, a legislative exemption of "black box" technologies would compete more effectively with proposals such as the Archer bill which exempts physician office labs entirely from CLIA oversight. If HCFA insists on including these initiatives, they need to better articulate why this approach to CLIA reform results in better test accuracy, health outcomes, and equivalent patient access compared to more radical approaches. Also, I continue to believe that HCFA's final Stark I rules will be inconsistent with HCFA initiatives providing more CLIA flexibility. For example, a midwife cannot perform microscopy testing without physician supervision and expect Medicare reimbursement under Stark I's inoffice ancillary services exception. Therefore, Stark I policies diminish the impact of HCFA's CLIA reforms. Finally, HCFA uses the phrase "Proposed rules are being finalized." This is confusing. It could mean that HCFA is developing proposed rules OR final rules. HCFA should be more precise and say that proposed rules are under development and will be submitted for OMB E.O. review by ..... or will be published by . . . .

. Outcome Performance Measures (pp. 11-14) - Before using these initiatives, HCFA should provide extensive assurances that recent issues with the nursing home industry and its enforcement rules will not spill over into other provider initiatives. Second, the time line for adopting performance standards is critical. If the time frame is not reasonable and within the bounds of this Administration, these may not be particularly impressive for roll-out. Third, in regard to end stage renal disease facilities, HCFA admits that the proposed "pilot" will not be generalizable. It is difficult to believe that this would be perceived as an outstanding reform initiative. Fourth, HCFA offers "certificates of excellence" to ESRD facilities that perform well. Has HCFA considered more flexible enforcement, i.e. rewards that offer tangible financial and hassle relief (rather than just another marketing gimic)?

. 50/50 Waiver for Medicare Managed Care (p. 15) - This is the first time I have seen this proposal on paper. I believe it has potential. I only wish that it wasn't limited to just rural managed care. Also, some "minimal" commercial enrollment still will be required. How "minimal" will it be?

. HCFA-1500 Form (p. 16) - HCFA should work with OPM to get an estimate for the timing so it can be released in the roll-out.

. Resident Review Requirements (p. 17) - HCFA should try to provide an estimate of the reduction in burden (it could be a range), explain whether this is a regulatory or legislative

change, and commit to a timeframe.

Distribution:

TO: Sally Katzen

CC: James B. MacRae Jr.
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CC: Phyllis E. Kaiser-Dark
CC: Lisa M. Jones
CC: Kamarck, Elaine C.
CC: Mary W. Poag

DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Executive Secretariat

FACSIMILE

PLEASE NOTIFY OR HAND-CARRY THIS TRANSMISSION TO THE FOLLOWING PERSON AS SOON AS POSSIBLE:

Name: Jennifer Klein

Address: _____

_____

_____

Message: _____

_____

_____

_____

_____

_____

Telephone: Office: 202 456-2599 FAX: 202 456-2878

Number Of Pages Being Transmitted (Including This One) 28

FROM: Jacquelyn White

FAX NUMBER: 202 690-7203
OFFICE NUMBER: 202 690-6111

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

July 3, 1995

NOTE TO: DIANA FORTUNA
JENNIFER KLEIN

SUBJECT: Update on the Rollout of the Nursing Home Survey and Enforcement Regulation

DISCUSSION

The Chief Of Staff requested that I provide you with background materials on the above mentioned issue.

Last week the American Health Care Association (AHCA) issued a memo to its board members that announced AHCA had reached an agreement with HCFA on the implementation of the Nursing Home Survey and Enforcement Regulation. This memo was interpreted to mean that HCFA had agreed to delay the implementation. To counter this impression, HCFA issued a statement and fact sheet restating our plans.

- On Monday, June 26th, Paul Willging, Executive Vice President, AHCA, sent a memorandum (Attachment A) to his board of directors and state executives entitled "HCFA Accepts AHCA Plan for Phased-In Implementation of Enforcement."

- Some AHCA members interpreted Willging's memo to mean that HCFA was delaying enforcement of the regulation (Example in Attachment B) and told state agencies about the delay.

- Late Tuesday, to counter the erroneous impression left by Willging's memo, HCFA released a statement by Bruce Vladeck (Attachment C) to *USA Today* and also sent it to key Hill offices. Attachment D is a *USA Today* article that ran on Wednesday.

- On Wednesday the statement and an updated fact sheet (Attachment E) were made available upon request to the press.

- HCFA is developing a fact sheet (Attachment F is a draft) that is tailored specifically for Hill and NGA staff.

- If you have any additional questions, please let me know.

Jacquelyn White
Deputy Executive Secretary
to the Department

TAB A

FAXED 6/26/95

MEMORANDUM

TO: Board of Directors
State Executives

FROM: Paul R. Willging, Ph.D.
Executive Vice President

SUBJECT: HCFA Accepts AHCA Plan for Phased-in Implementation of Enforcement

DATE: June 26, 1995

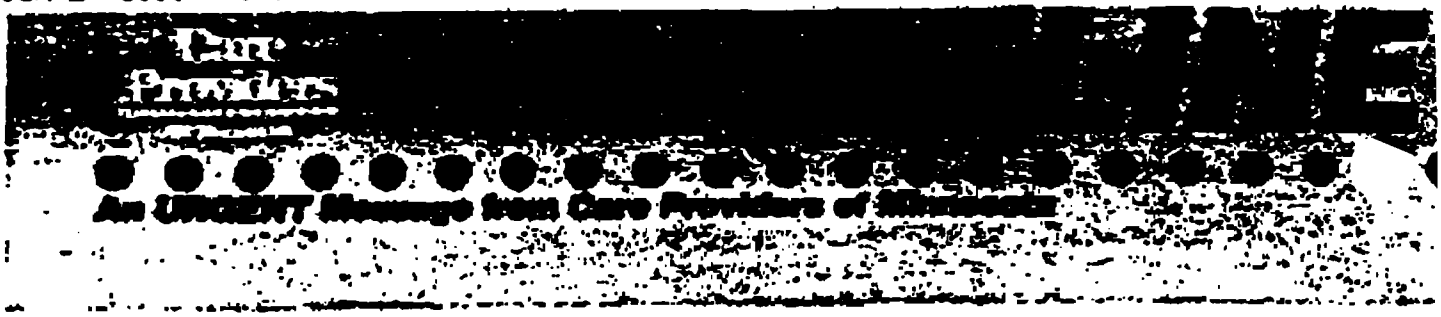
After weeks of intense lobbying by the American Health Care Association at the administrative and Congressional levels, the Health Care Financing Administration has agreed to adopt a phased-in implementation of the enforcement provisions of the final survey, certification and enforcement rule, slated for implementation on July 1, 1995. My thanks to all of you who worked so hard with your congressional delegation to achieve this result.

Under the agreement, neither HCFA nor the states will impose a civil money penalty or any other category two or three remedy, except in cases of immediate jeopardy or facilities considered to be chronic poor performers, until such time as a sufficient number of surveys have been completed to allow analysis of the enforcement process and both HCFA and an oversight panel appointed by HCFA have reviewed the data collected to determine whether revisions are needed to the enforcement system. Category two and three remedies include denial of payment for new admissions; denials of payment for all admissions (a HCFA remedy only); civil money penalties (all ranges); temporary management and termination.

If a faculty is found out of compliance during the test and review period, and remains out of compliance after the test period ends, penalties will be imposed back to the date of the original survey which found the none compliance.

The tentative oversight panel which HCFA will appoint will include the American Health Care Association; surveyors; consumers; ombudsmen; a beneficiary; a medical director; and a nurse. HCFA has indicated that all members of the oversight panel will have the opportunity to communicate problems and issues they observe during the test period to HCFA officials. Other details of the agreement, including the mechanics of the oversight process are still being ironed out with HCFA. We will keep you updated as more information becomes available.

TAB B



Date: June 26, 1995

To: Care Providers of Minnesota Members

From: Rick E. Carter, President

Re: **HCFA Agrees To Partial Delay In Survey Enforcement Sanctions**

The Health Care Financing Administration (HCFA) will partially delay enforcement of the two highest penalty categories in the new survey process which will begin on July 1, 1995. This partial delay comes after intense grassroots lobbying by Care Providers of Minnesota and the American Health Care Association (AHCA) who maintained that many high performing nursing facilities would be falsely identified as providing substandard care due to HCFA's definition of "harm."

While the new survey process and interpretive guidelines will go forward without change on July 1, 1995, there is a partial delay in the implementation of the enforcement regulations. HCFA finally agreed that it would make some sense to study the first surveys conducted under the new survey process to determine if the definitions of "minimal harm" and "actual harm" need to be revised. An AHCA "harm" study conducted earlier this year found that 24% of all U.S. nursing facilities would fall into the category of "substandard quality of care." Recent mock surveys in Minnesota confirmed AHCA's claims that the new survey system will paint an inaccurate picture of the quality of care. In ten "pretend" facility surveys, seven facilities would have been issued deficiencies classifying them as providing a substandard level of care.

The language of the agreement between HCFA and AHCA as of Friday, June 23 states that:

> "Except in cases of immediate jeopardy and chronic poor performance, no nursing facilities will pay a Civil Money Penalty (CMP) or incur any other category (2) or (3) remedy until a sufficient number of completed surveys have been collected to allow analysis of the process; individuals assessing the impact have had an opportunity to review the data collected; and HCFA has had the opportunity to do the same, and determine whether the data indicates the need to make any revisions to the enforcement system. Thereafter, nursing facilities still out of compliance will be liable for penalties with an effective date back to the last day of the survey. Each person assessing the impact will communicate to the HCFA Administrator problems he or she sees arising during the early stage of the enforcement process. These individuals shall have access to all information contained in the statement of deficiency (HCFA Form 2567L) and all other data not otherwise protected by privacy laws."

The definitions that are important to note are "immediate jeopardy" and "chronic poor performance."

"Immediate jeopardy" means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

"Poor performing facility" means a facility with a history of "in" and "out" compliance and/or a facility that has no system in place to monitor its own compliance. A poor performing facility has no opportunity to correct and is only entitled to minimum notice requirements.

HCFA is now in the process of selecting consumer, provider, and survey agency representatives to participate in a national task force to review the statements of deficiencies. This task force will then determine whether changes should occur in the current enforcement process. Care Providers of Minnesota will be collecting 2567L forms to assist AHCA in its monitoring/study activities. I strongly encourage member facilities to participate in this effort to evaluate the effectiveness of the new survey process. (We will inform members through a special letter and in upcoming *ACTION* articles on the progress of this activity.)

Although the partial delay is a significant event, providers still need to be cautious for the following reasons:

- Category 1 remedies are still in effect (directed plan of correction, state monitor and/or directed in-service training from a third party).
- Facilities that fall under either of the above definitions (immediate jeopardy or poor performing) will still be subject to the higher remedies.
- If it is determined during the study that the definitions and enforcement process should stand intact as currently written, the remedies can still be applied retroactively.

More Details Available at Seminar This Friday

More details and information will be available at the Survey, Certification, and Enforcement Seminar being held this Friday in Alexandria, Minnesota. Care Providers of Minnesota is also preparing additional educational seminars later this summer on the new survey , certification, and enforcement process. For registration information on Friday's seminar and other education programs, contact Shirley Henning at the Association office.

I want to thank you for the letters and phone calls to Minnesota's congressional delegation in Washington, D.C. As a result of our strong grassroots lobbying in Minnesota, and many other states, HCFA was deluged with congressional inquires about the new survey process. For more information contact Patti Cullen at (612) 854-2844 or 1-800-462-0024 toll free.

TAB C

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Tuesday, June 27, 1995

Contact: HCFA Press Office
(202) 690-6145

STATEMENT BY BRUCE C. VLADECK
Administrator, Health Care Financing Administration

"As Secretary Shalala made clear earlier this month, the Health Care Financing Administration is proceeding on schedule with the implementation of the Nursing Home Survey and Enforcement regulations on July 1. These regulations represent the final step in bringing about nursing home reform and assuring high quality care for nursing home residents.

"As has been the case throughout the process of developing and implementing these regulations, we are committed to extensive public consultation and interaction with all interested parties. In addition, we are planning very extensive monitoring of the implementation process, and we will be prepared to make such adjustments in our policies and procedures as we determine may be needed.

"In any situation of 'immediate jeopardy,' or in the case of chronic offenders, HCFA and the states would act immediately and decisively to protect nursing home residents by imposing sanctions. For other nursing homes, however, our regulations provide a period of time during which penalties would not be collected. This provision was included in our regulations because it puts the emphasis on correcting problems, not simply assessing fines. One effect of this provision will be that no fines will be collected during the first 90 days of implementation. Thus, during this initial implementation period, we will have time to observe the regulations in action before any fines must be collected.

"Our ultimate goal is a collaborative effort between industry, consumers and government to deliver high quality care to nursing home residents. No nursing home which fails to meet quality standards will be immune from the appropriate sanctions. Likewise, no nursing home which meets the standards will be subject to any penalties."

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TAB D

USA Today; 6-28-95

Nursing home reforms at risk

Industry, lobbyists, White House at odds

By Peter Eisler
USA TODAY

2A

Charges of backroom deals and broken promises are clouding the Clinton administration's push to end a seven-year delay in implementing rules to crack down on shoddy nursing homes.

The administration has set a July 1 deadline for adopting the rules, which would impose stiff fines and tough sanctions on homes that mistreat patients.

But both the nursing home industry and the consumer groups that usually fight it now are angry at the White House, with each side criticizing what it sees as double-dealing in negotiations over the rules' content.

"All the delays have increased the pressure enormously, and it's compounded by the fact that all of this is being done in secret," said Sarah Burger of the National Citizens Coalition for Nursing Home Reform. "We're very wary."

So is the nursing home industry, which says that initial drafts of the new rules were too tough, leaving about eight of every 10 nursing homes to face fines or other penalties for what the industry says are, in most cases, minor offenses.

Tuesday, the behind-the-scenes simmer came to a public boil:

Clinton administration officials angrily denounced the nation's largest nursing home lobby group for circulating a memo — obtained by USA TODAY — that said the administration had, in effect, caved to industry pressure and would delay putting the new rules in place.

"After weeks of intense lobbying ... at the administrative and congressional levels, the Health Care Financing Administration has agreed to adopt a phased-in implementation of the enforcement provisions" of the new rules, the American Health Care Association memo said.

But Health Care Financing Administration officials, in charge of drafting the rules, said there will be no delay and no such deal had existed.

In the end, the rules will be implemented, the officials said, but no fines will be collected until the new rules' effect is reviewed by a yet-to-be-appointed panel.

"This provision was included ... because it puts the emphasis on correcting problems, not simply assessing fines," said administrator Bruce Vladeck. "We will be prepared to make ... adjustments in our policies and procedures as we determine may be needed."

The Health Care Financing Administration is writing new rules because it oversees Medicare and Medicaid; about 85% of all nursing homes receive funds under those programs. The goal of the rules is to put muscle in nursing home reforms passed by Congress in 1987.

Spurred by widespread reports of patient abuse and neglect, the reforms initiated new care standards, set minimum staff training requirements and began a process of regular nursing home inspections by government surveyors.

But Congress left it to the Health Care Financing Administration to spell out details — and the many reforms were not enforced.

The Bush administration never put them in place. And the Clinton administration's already difficult task in doing so now has been complicated by the new anti-regulatory climate on Capitol Hill.

The danger: make the rules too tough, and the Republican majority in Congress could decide to rewrite the entire nursing h e reform law on which they are

Earlier this month, Senate Majority Leader Bob Dole, a presidential hopeful, told the American H Care Association that nursing regulations should be eased.

"Many of us think we ought to go back and take some of the h you're burdened with out" of the law, Dole said at the time.

Those kind of sentiments have given the nursing home industry negotiating power.

"Before you start fining facilities, make sure you're actually fining poor providers," said Linda Keegan, vice president of the nursing e lobby.

By Rick Wilking, Reuters

CLINTON: Administration denies caving in to industry pressure

By Tim Dillon, USA TODAY

DOLE: Says nursing home industry should be less 'burdened'

TAB E

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

June 1995

Contact: HCFA Press Office
(202) 690-6145

NURSING HOME REFORM:
FLEXIBLE ENFORCEMENT RULES TO ENSURE HIGH QUALITY CARE

Overview: As of July 1, 1995, HHS is implementing the last major phase of nursing home reform. On that day, new enforcement regulations take effect to assure high quality care in nursing homes.

Nursing home reform has been put into effect in phases by HHS' Health Care Financing Administration, working in cooperation with nursing home providers as well as organizations representing Medicare and Medicaid beneficiaries.

To date, reform has included a residents' "bill of rights" and requirements for individual resident assessments and plans of care, as well as nurse aide training and competency requirements and the establishment of a nurse aide registry. Now, with the new enforcement regulations, a wider range of sanctions will be available, tailored to different kinds of quality problems.

The new enforcement rules provide a variety of remedies that can be applied for deficiencies of varying severity. Adopting "substantial compliance" as the acceptable standard, the new rules are meant to ensure reasonable regulation, while at the same time they require nursing homes to fix problems quickly and on a long-term basis. An important goal of the new enforcement plan is to ensure that continuous internal quality control and improvement is performed by nursing homes themselves. HCFA is working closely with states, providers and beneficiary groups as the new enforcement regulations are implemented.

Nursing homes at a glance:

Number of nursing home residents:	*1.5 million*
Number of nursing homes:	*16,700*
Annual nursing home spending:*	*$40 billion*

*(*FY'95 estimate, Medicare/Medicaid-federal & state)*

BACKGROUND

- Nursing home reform was the result of the Institute of Medicine's (IoM) study of the regulation of nursing homes, entitled, *"Improving the Quality of Care in Nursing Homes,"* published in 1986. The study culminated in the passage of reform legislation in the Omnibus Budget Reconciliation Act of 1987. Nursing home reform resulted in a new set of outcome-based requirements which have been in effect since 1990.

- A primary focus of the IoM study was the chronic problem of nursing homes that fail to comply with federal requirements and the manner in which "borderline" nursing homes were in and out of compliance with Medicare and Medicaid health and safety participation requirements. The IoM found that many of these facilities could avoid termination of participation if they came into compliance long enough to be recertified, but that these facilities had no commitment to sustained compliance. Therefore, the study recommended that HCFA implement a range of intermediate remedies to deter violations.

- HCFA's new long term care enforcement regulation implements the nursing facility reform legislation passed by Congress. The legislation mandated the abandonment of HCFA's traditional methodology of responding to deficiencies, which relied primarily on a single severe sanction: termination of payment for Medicare and Medicaid patients. The new variety of remedies allows HCFA or the state to tailor the particular remedy to the seriousness of the violation.

- The proposed enforcement rule was published in the Federal Register on August 28, 1992. HCFA considered 28,000 comments received during the comment period, including all concerns raised by industry, advocates, and beneficiaries, in the creation of improved measurements of compliance. The final regulation was published in the Federal Register on November 10, 1994.

- The regulation provides for the imposition of civil money penalties and other alternative remedies, such as denial of payment for new admissions, state monitoring, temporary management, directed plans of correction, and directed in-service training. At the same time, the enforcement regulation requires that all violations be addressed, employing a remedy that is appropriate to the severity of the problem.

- To implement the law and regulations, a workgroup comprised of state, regional, and central office representatives created the State Operations Manual instructions for the new enforcement system. The manual instructions were then circulated for comment. HCFA has addressed and incorporated comments and suggestions received from industry representatives, consumer advocates, and internal partners such as states and regions.

- The final enforcement regulation is effective July 1, 1995.

GOALS

- The enforcement regulation establishes attainable compliance standards for Medicare/Medicaid providers. Perfect compliance is not a realistic expectation. Facilities are, however, expected to achieve substantial, continued compliance and take an active stance in quality assurance and improvement, with ongoing efforts at internal quality control. The enforcement process, including definitions of scope and severity, was developed in partnership with provider and beneficiary groups.

- HCFA recognizes that one enforcement response is not appropriate for all deficiencies. The new regulation provides alternatives to termination and denial of payment for addressing noncompliance. Sanctions are commensurate with the level and pervasiveness of harm.

- HCFA has four goals in implementing the final rule. These goals are key to the success of the overarching objective -- continuous improvement in the quality of nursing home care.

  1. *Motivate facilities to remain in compliance*. Enforcement process can result in remedies for noncompliance. A facility cannot wait for a state to act as its quality assurance program by identifying deficiencies on the survey, then fix it without a remedy.

  2. *Promote survey and enforcement consistency*. Requires that studies be conducted, education programs be provided, and mandatory surveyor training and testing be completed. An enforcement model to assess deficiencies and select remedies is used to guide decision making.

  3. *Link enforcement responses to deficiencies*. Puts enforcement remedies into three remedy categories, and each remedy category is associated with specific levels of noncompliance. Makes a correlation between the seriousness of noncompliance and the enforcement response.

4. *Create no unnecessary processes*. Informal dispute resolution process should reduce burden of formal mechanism and will not delay enforcement remedies. The existing enforcement remedies are blended into the new enforcement model.

WHAT THE REGULATION DOES

- Expands the menu of remedies that can be imposed instead of, or in addition to, termination.
- Uses substantial compliance as the standard of compliance. Substantial compliance means that a provider's deficiencies pose no more than a potential for minimal harm. Providers in substantial compliance are certified in compliance and are not subject to enforcement remedies.
- Uses severity and pervasiveness to determine appropriate remedies.
- Discourages "yo-yo compliance" by providing for the imposition of a civil money penalty upon identification of current noncompliance as well as periods of noncompliance between two certifications of compliance. Poor performers who come into compliance only long enough to be recertified, but who don't sustain compliance, can be sanctioned quickly.
- Codifies informal dispute resolution. Providers have an opportunity to dispute survey findings to the State or regional office. This informal review will not delay enforcement actions.

PARTNERSHIP: TRAINING AND ASSISTANCE

- An intense and wide-ranging training initiative has been carried out to prepare for implementation of the new enforcement regulations. HCFA has worked with states and with private industry to assure preparedness.
- HCFA is also establishing unprecedented procedures, including early alert systems, to monitor implementation and ensure that the new rules work as intended to ensure high quality care.
- The actual requirements that nursing homes must meet (the nursing home certification rules) have been in effect nearly five years, and during this time providers have received extensive training on those requirements.

o *The training initiative has been extensive:*

-- State and regional trainers responsible for educating the surveyors and personnel in their districts attended training provided by HCFA central office in Baltimore, MD. The four one-week training sessions were offered between April 3 and May 12, 1995.

-- Industry and advocacy representatives attended each training session and offered evaluative comments and suggestions for the improvement of materials and presentations.

-- States and regions have also been training personnel in preparation for the July 1, 1995, effective date. HCFA central office staff attended state and regional training sessions to gauge the consistency and effectiveness of this second stage of training.

-- HCFA developed videos and training materials to standardize the field training and provide instructors with consistent, accurate information about the new enforcement system.

o *HCFA will monitor the implementation closely and work in partnership with private industry:*

-- The implementation of the nursing home enforcement regulation is planned so that nursing home residents are assured access to high quality care and nursing homes will have safeguards to protect them from the imposition of inappropriate or unnecessary remedies.

-- Almost all facilities will be given the opportunity to correct the deficiencies and avoid remedies. The structure of the enforcement process provides that remedies (including civil money penalties) will not take effect for the first 90 days after the July 1 implementation date. Only those chronic poor performers and those with deficiencies presenting immediate jeopardy will be assessed an immediate remedy, including civil money penalties.

-- HCFA plans to gather extensive data on implementation, and use this information to concentrate educational efforts and fine tune the enforcement process. Federal surveyors will accompany state surveyors to observe and assure national consistency.

-- A Council of Observers representing consumers, providers and professional groups will provide feedback during the early implementation.

-- HCFA is establishing an E-mail station to collect and answer implementation questions from the States and regions. In addition, central office will conduct weekly conference calls with the regions dedicated to implementation issues and updates.

-- A "situation room" will be dedicated as a central control point for monitoring implementation and communicating with States and regions on a daily basis.

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TAB F

DRAFT

Implementation of the Final Rule for Survey, Certification and Enforcement for Nursing Homes

Summary

- In response to often deplorable conditions in the nation's nursing homes, the Congress enacted landmark reform legislation in the Omnibus Budget Reconciliation Act of 1987. The rule on survey and enforcement completes the comprehensive reform started in 1986.

- The OBRA '87 legislation raised the standards for nursing home care. These higher standards have been in effect since October 1, 1990, and will be enforced through this regulation. Reimbursement to nursing homes was increased to reflect the cost of compliance with these new standards.

- The enforcement regulation, published in November 1994, is scheduled to take effect on July 1, 1995. Only about one-twelfth of the nation's nursing homes will be surveyed in July.

- The enforcement process, including the definitions for the scope and severity of harm to residents, was developed in partnership with provider and beneficiary groups during a series of meetings.

- No fines or other remedies will take effect for most facilities during the first 90 days of implementation. Therefore, HCFA will have time to monitor the regulations and identify any problems during this initial implementation period before any fines are collected.

  Almost all facilities will be given the opportunity to correct their deficiencies and thereby avoid remedies. However, chronic poor performers and those with deficiencies presenting immediate jeopardy will not only be required to correct the deficiencies, but will also be assessed immediate remedies, including civil money penalties.

- Both the Secretary of DHHS and the Administrator of HCFA are personally committed to monitoring the implementation to ensure that both providers and consumers are not adversely impacted. A "situation room", staffed by HCFA and state experts in nursing home regulation, will promptly identify problems and provide guidance to the field. HCFA will conduct on-site reviews to ensure consistent interpretations of survey instructions and assess areas of concern about the revised protocol. Some of the Nation's leading nursing home care providers, consumer advocates and state regulators will offer their assessments of the impact of the implementation and help to identify any problems that arise during the early stages of implementation.

Philosophy Rooted In OBRA '87 Nursing Home Reforms

- In response to often deplorable conditions in the nation's nursing homes identified in a 1986 report from the Institute of Medicine, the Congress enacted landmark reform legislation in the Omnibus Budget Reconciliation Act of 1987 (further amended in 1988, 1989, and 1990 legislation).

- OBRA '87 was implemented through a number of nursing home reform regulations designed to help ensure that residents receive the care and services they need to meet their highest practicable level of functioning; that nursing homes remain in substantial and continual compliance with program requirements; and that each facility maintains a strong, functioning quality assurance program.

- A number of regulatory actions were required to implement the nursing home reform provisions. New, higher standards, designed to improve the quality of life and quality of care for the nation's 2.1 million frail and elderly nursing home residents, took effect on October 1, 1990. Reimbursement to nursing homes was increased to reflect the cost of compliance with these new standards.

- The final regulation on survey and enforcement completes the comprehensive reform mandated by the reform law. The system established under this regulation provides authority for various remedies that can be imposed if nursing homes do not meet standards of care incorporated in the requirements for participation in the Medicare and Medicaid programs, which together pay over $40 billion annually for nursing home care. The final regulation was published in the Federal Register on November 10, 1994.

- The final regulation is intended to:
  - Motivate facilities to remain in compliance.
  - Promote survey and enforcement consistency.
  - Link enforcement responses to deficiencies.
  - Avoid the creation of unnecessary processes.

- The regulation is scheduled to take effect on July 1, 1995.

- The implementation of the nursing home enforcement regulation is a work in progress. HCFA will monitor the implementation of this system very closely and adjust procedures to resolve any operational problems as they appear.

Phased-in Implementation

- This regulation enforces standards that have been in effect since October 1990.
- This regulation was published in final in November 1994. The effective date was delayed precisely to insure that HCFA and the nursing home industry had time to prepare for the new enforcement procedures.
- Given the normal survey schedule, only one-twelfth of the nation's nursing homes will be surveyed in July, and each month thereafter.

Partnership - The Key to Effective Regulation

- The enforcement process, including the definitions for the scope and severity of harm to residents, was developed in partnership with provider and beneficiary groups over a number of months culminating in a series of consensus meetings conducted during March 1995.
- A work group comprised of State, and HCFA regional and central office representatives created the State Operations Manual Instructions for the new enforcement system. The manual instructions address comments and suggestions received from industry representatives, consumer advocates, and other internal partners.

"Harm" Defined by a Scope and Severity Scale

- The American Health Care Association estimates and is concerned that over 80% of nursing home will be found out of compliance under the new enforcement system. In fact, of that 80% almost all facilities will be given the opportunity to correct their deficiencies and avoid sanctions. Only those chronic poor performers and those with deficiencies presenting immediate jeopardy will be assessed an immediate remedy, including civil money penalties.
- The degree of harm to a nursing home resident caused by a deficiency is defined by a scope and severity scale (see attachment). A work group of State and HCFA regional and central office staff, as well as nursing home representatives and consumer groups, developed definitions to accompany the scope and severity scale. They include the following definition of *actual harm that is not immediate jeopardy to the health and safety of the residents*:

- "Non-compliance that results in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental and psychosocial well being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. This does not include a deficient practice that only has limited consequence for the resident."

- Illustrative examples of varying levels of harm and the resulting remedies include:

Immediate jeopardy:

A facility fails to clear most fire exits several hours after a snow fall. Since residents would not be able to exit the building in the event of a fire or other emergency, this deficiency represents a severity of immediate jeopardy, and the scope of the deficiency is widespread, since all residents are potentially affected. Under the current system, if the facility fails to correct, the only available enforcement option is termination. Under the new rules, if the facility fails to correct within the limited time available, the facility will be subject to one or more remedies, one of which must be either temporary management or termination. The facility could also be subject to a civil money penalty of $3,050 to $10,000 per day of noncompliance.

Actual harm that was not an immediate jeopardy:

Example 1:

A nursing facility failed to provide a large group of residents with care and services needed to maintain grooming and hygiene andsupport resident dignity. These residents, many of whom were incontintent and were totally dependent on staff for care and services, had oily hair, poor oral hygiene, inflamed gums, and strong body odor. Incontinent residents were often left in public areas for long periods of time with soiled clothing. Surveyors also found that a strong urine odor permeated the facility.

This deficiency represents a severity of actual harm that was not an immediate jeopardy. Since the deficiency affected a large number of residents in the facility, the scope of the deficiency was widespread. Under the current system, we would request correction, but no remedy is imposed for failure to correct. Under the new rules, if the facility fails to correct the deficiency within the time available, one or more remedies will be imposed, and may include denial of payment for new admissions, denial of

payment for all individuals, or a civil money penalty of $50 to $3,000 per day of noncompliance.

Example 2:

A diabetic resident who should get insulin at 6:30 a.m. does not. At 10:30 a.m., she shows signs of a diabetic reaction. This deficiency represents a severity of actual harm that was not an immediate jeopardy. Since she was the only resident affected, the scope of the deficiency was isolated. Under the current system, we would request correction, but no remedy is imposed for failure to correct. Under the new rules, if the facility fails to correct the deficiency within the time available, one or more remedies will be imposed, and may include denial of payment for new admissions, denial of payment for all individuals, or a civil money penalty of $50 to $3,000 per day of noncompliance.

No actual harm with a potential for minimal harm:

A physician caring for 10 percent of the residents fails to visit them within prescribed timeframes. This would be considered a severity level of "harm 1" (no actual harm with a potential for minimal harm) and the scope represents a pattern. Both under the current system and under the new rules, this facility would not be subject to an enforcement remedy, but would be required to develop a plan of correction to keep the situation from reoccurring.

Flexibility Granted to Providers

- Three key elements of the enforcement strategy will give facilities flexibility: substantial compliance, informal dispute resolution, and date certain.
  - "Substantial compliance" is the standard for certifying nursing homes. Minimal deficiencies will not be cause for denying certification or imposing other remedies. In other words, a facility may be out of compliance with some Medicare and/or Medicaid requirements, but still be in substantial compliance, depending on which requirements are not met and to what extent.

- The regulation requires States to give facilities an opportunity to contest the existence of deficiencies on the basis of the survey findings through an informal dispute resolution process. Formal appeal mechanisms are also available.

- The majority of facilities will get an opportunity to correct deficiencies and, if corrected, avoid remedies.

  On a "date certain", if the facility has not achieved substantial compliance, the State survey agency (SA) will recommend that the HCFA Regional Office or State Medicaid Agency impose remedies. If substantial compliance is achieved, remedies are not recommended.

  It is likely that the majority of nursing homes will come into and remain in substantial compliance prior to the date certain and avoid the imposition of remedies. However, facilities found to have an "immediate jeopardy" to resident health and safety and those identified as chronic "poor performers" will not get an opportunity to correct before remedies are imposed.

Extensive training initiative

- State and HCFA personnel have been training surveyors, providers and consumer advocates in preparation for the July 1, 1995, effective date. HCFA developed videos and training materials to standardize the field training and provide instructors with consistent, accurate information about the new enforcement system.

- HCFA will address early implementation issues requiring further clarification or refinement through the development of training videotapes and a national satellite broadcast during the latter part of September 1995. Additional follow-up training programs will also be developed.

More Tools For Surveyors

- Previously, the only enforcement actions available when a facility was out of compliance with participation requirements were termination or denial of payment for new admissions. This regulation recognizes that a single enforcement response is not appropriate for all deficiencies, and provides alternatives to termination and denial of payment in the case of noncompliance. The regulation provides the flexibility in each case to apply a remedy that fits the scope and severity of the problem. The regulation provides the flexibility in each case to apply a remedy that fits the scope and severity of the problem. Available remedies, listed from least severe to most severe, include:

- Monitoring by State Survey Agency
- directed plan of correction
- directed in-service training of staff
- denial of payment for new admissions
- denial of payment for all individuals
- civil money penalties
- temporary management
- termination from the Medicare/Medicaid programs and
- closure and/or transfer of residents.

Civil Money Penalties

- The regulation discourages "yo-yo compliance" by providing for the imposition of a civil money penalty (CMP) upon identification of current noncompliance as well as periods of noncompliance between certification periods. Poor performers who come into compliance only long enough to be recertified, but who do not sustain compliance, can be sanctioned quickly.

- A CMP can be imposed within two ranges. The upper range is from $3,050 to $10,000 per day of noncompliance for deficiencies constituting immediate jeopardy (severity level 4, regardless of scope level). The lower range is from $50 to $3,000 per day of noncompliance for deficiencies constituting non-immediate jeopardy (severity level of 2 or 3, regardless of scope level)

- A CMP may be imposed for the number of days that a facility is not in substantial compliance with one or more participation requirements, regardless of whether deficiencies constitute immediate jeopardy or not. A CMP may also be imposed for egregious past noncompliance that falls between 2 certifications of compliance.

- While a CMP may be imposed for the number of days that a facility is out of compliance, the majority of facilities will be given an opportunity to correct before a CMP is imposed; therefore, we expect that these facilities will be able to achieve substantial compliance before the imposition of the remedy.

Implementation: "Partners for Better Care"

- The implementation of the nursing home enforcement regulation is planned so that nursing home residents are assured access to high quality care and nursing homes will have safeguards to protect them from the imposition of inappropriate or unnecessary remedies.

- The structure of the enforcement process provides that remedies (including civil money penalties) will not take effect for the first 90 days after the July 1 implementation date.[1]

- HCFA will establish a "situation room" staffed by individuals with expertise in nursing home regulation to promptly identify problems and controversial issues and provide guidance for HCFA field staff. HCFA staff will conduct onsite observations with state survey teams to ensure consistent interpretations of survey instructions and assess areas of concern about the revised protocol. In addition, HCFA will collect and analyze data regarding survey findings and proposed remedies.

- During the initial months of the implementation, copies of the statements of deficiencies and other survey documents that cite substandard quality of care or other significant findings will be sent to the "situation room." The documents will be reviewed and analyzed to ensure appropriate and consistent interpretation of definitions or to identify any problems with the definitions. HCFA's reviews will be completed before a remedy is imposed.

- To assess the impact of the nursing home enforcement regulation implementation, HCFA is consulting some of the nation's leading nursing home care providers, consumer advocates, and state regulators. These individuals will assist the Secretary and the HCFA Administrator in identifying any problems that arise during the early stages of the enforcement process. The analysis of the data will be provided to senior officials and the individuals assessing the implementation for review and discussion. Senior officials will take any action they determine is needed such as surveyor training, clarifications/refinements of definitions used in implementing the enforcement regulation, or issuance of emergency rules to maintain the integrity of the health care system in the delivery of nursing home services.

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[1] Immediate jeopardy and poor performing facilities not included. Immediate jeopardy procedures have not been changed. The requirements for immediate corrective action to remove jeopardy continues in effect. Facilities with a history of significant deficiencies during previous survey periods will also be subject to the immediate imposition of remedies.

Attachment

DEFINITIONS OF SEVERITY

NO ACTUAL HARM WITH POTENTIAL FOR MINIMAL HARM: A deficiency that has the potential for causing no more than a minor negative impact on the resident(s).

NO ACTUAL HARM WITH POTENTIAL FOR MORE THAN MINIMAL HARM THAT IS NOT IMMEDIATE JEOPARDY: Non-compliance that results in minimal physical, mental and/or psychosocial discomfort to the resident and/or has the potential (not yet realized) to compromise the resident's ability to maintain and/or reach his/her highest practicable physical, mental and/or psychosocial well being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.

ACTUAL HARM THAT IS NOT IMMEDIATE JEOPARDY. Non-compliance that results in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental and psychosocial well being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. This does not include a deficient practice that only has limited consequence for the resident and would be included in level 2 or in level 1.

IMMEDIATE JEOPARDY TO RESIDENT HEALTH OR SAFETY. A situation in which immediate corrective action is necessary because the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility.

DEFINITIONS OF SCOPE

ISOLATED: Scope is isolated when one or a very limited number of residents are affected and/or one or a very limited number of staff are involved, and/or the situation has occurred only occasionally or in a very limited number of locations.

PATTERN: Scope is a pattern when more than a very limited number of residents are affected, and/or more than a very limited number of staff are involved, and/or the situation has occurred in several locations, and/or the same resident(s) have been affected by repeated occurrences of the same deficient practice. The effect of the deficient practice is not found to be pervasive throughout the facility.

WIDESPREAD: Scope is widespread when the problems causing the deficiencies are pervasive in the facility or represent systemic failure and affect, or have the potential to affect, a large number of residents in the facility.