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CONTACT: HCFA Press Office
(202) 690-6145

ASSURING THE QUALITY OF NURSING HOME CARE

The Clinton Administration, continuing its strong commitment to ensuring high quality nursing home care for those who need it, announced new steps today to ensure that all nursing home residents are treated with dignity and compassion.

Since 1995, the Administration has been enforcing the toughest nursing home regulations in the history of the Medicare and Medicaid programs. Working with States, who have the primary responsibility for conducting on-site inspections and recommending sanctions, the Health Care Financing Administration has sharply increased the number of penalties levied on poor-quality nursing homes. In a new report to Congress, HHS notes significant improvements in the quality of care delivered in nursing homes. But the report also finds a need for further improvement by States, nursing homes, and others.

As part of its new initiative, the Administration will work with the States to improve their nursing home inspection systems; crack down on nursing homes that repeatedly violate safety rules; require nursing homes to conduct criminal background checks on all new employees; reduce the incidence of bed sores, dehydration, and malnutrition; and publish nursing home quality ratings on the Internet.

Background

About 1.6 million elderly and disabled people receive care in approximately 16,800 nursing homes across the United States. The Federal government, through the Medicare and Medicaid programs, provides funding to the States to conduct on-site inspections of nursing home participating in Medicare and Medicaid and to recommend sanctions against those homes that are violating health and safety rules. Since 1995, the Health Care Financing Administration (HCFA) has had the authority to levy harsher penalties on nursing homes found out of compliance with those rules.

In 1986, the Institute of Medicine issued a landmark report detailing the often deplorable conditions in our nation's nursing homes. That report led to the enactment of historic legislation, the Omnibus Budget Reconciliation Act of 1987, which reformed the way States and the Federal government oversee nursing homes and protect the health of residents. The legislation

established new standards for quality, a set of resident rights, a new system to assess the quality of nursing home residents' lives, and a new survey mechanism focused on patient outcomes. The law also created new staffing requirements for licensed nurses and new training requirements for nursing assistants and others. And it established new, more flexible enforcement rules and penalties to help identify and punish nursing homes that violate the new rules. On July 1, 1995, the Clinton Administration implemented key provisions of the law through new Federal regulations.

Clear Evidence of Improvement, But Problems Persist

According to a new report to Congress, there is clear evidence that the new regulations are improving the health and safety of nursing home residents. Specifically:

- the overuse of anti-psychotics is down from about 33 percent before nursing home reform was implemented to 16 percent now;
- the appropriate use of antidepressants is up from 12.6 percent to 24.9 percent;
- the inappropriate use of physical restraints is down, from about 38 percent to under 15 percent;
- the inappropriate use of indwelling urinary catheters is down nearly 30 percent; and
- the number of nursing home residents with hearing problems who receive hearing aids is up 30 percent.

While there are improvements attributable to the new regulations, the HCFA report makes clear that several areas require greater attention. Among those findings are:

- State-run nursing home inspections are too predictable. Inspection teams frequently appear on Monday mornings and rarely visit on weekends or during evening hours. This allows nursing homes to prepare for inspections.
- Several States have cited few or no nursing homes for substandard care, an indication that their inspections and enforcement may be inadequate;
- Nursing home residents continue to suffer unnecessarily from such clinical problems as pressure or bed sores, malnutrition and dehydration. These can be easily prevented with proper care; and,

- Residents continue to experience physical and verbal abuse, neglect, and misappropriation of residents' property at the hands of unscrupulous nursing home personnel.

New Administrative Actions

As part of its nursing home continuous quality improvement strategy, the Administration is adding new enforcement tools and strengthening Federal oversight of nursing home quality and safety standards in the following ways:

- ◆ **Tougher Nursing Home Inspections.** HCFA will take several steps to improve States' inspection of nursing homes including:
 - ⇒ Inspections will be done more often for repeat offenders with serious violations without decreasing inspection frequency for other facilities;
 - ⇒ Survey times for all facilities will be staggered, with a set amount to be done on weekends and evenings.
 - ⇒ States will no longer be able to grant grace periods – which allow first-time offenders time to correct problems without penalty -- to nursing homes that have been cited twice as being out of compliance with Federal rules.
 - ⇒ Federal and State officials will focus on nursing home chains that have a record of noncompliance with Federal rules; and,
 - ⇒ HCFA will work HHS' Office of the Inspector General and the Department of Justice to refer egregious violations of quality of care standards for investigations and prosecution when appropriate.
- ◆ **Stronger Federal Oversight of State Inspections.** To target States with weak inspection systems, HCFA will:
 - ⇒ Provide additional training and other assistance to inspectors in States that are not adequately protecting residents;
 - ⇒ Enhance Federal review of the surveys conducted by the States;
 - ⇒ HCFA will assure that State surveyors enforce its policy to sanction nursing homes with serious violations and that sanctions cannot be lifted until after an onsite visit has verified compliance; and,

⇒ Terminate Federal nursing home inspection funding to States with continuing poor records and contract with other entities to conduct nursing home inspections in those States.

- ◆ **Preventing Bed Sores, Dehydration, and Malnutrition.** HCFA will step up its review of nursing homes' ability to prevent bed sores, dehydration, and malnutrition. Nursing homes with patterns of violations will be sanctioned. HCFA also will work with the Administration on Aging, the American Dietitians Association, clinicians, consumers, and nursing homes, to develop a repository of best practice guidelines for residents at risk of weight loss and dehydration.
- ◆ **Combating Resident Abuse.** State inspectors will review each nursing home's system to prevent, identify, and stop physical or verbal abuse, neglect, and misappropriation of resident property. Information about each nursing home's performance in this area will be shared with residents and their families. HCFA will also ask states to direct nursing homes to inquire about criminal convictions when interviewing potential personnel.
- ◆ **Publishing Survey Results on the Internet.** Individual nursing home survey results and violation records will be posted on the Internet to increase accountability and flag repeat offenders for families and the public.
- ◆ **Continuing Development of Minimum Data Sets.** In June 1998, HCFA began collecting information on resident care through a national automated data system, known as a Minimum Data Set. This information will be analyzed over time, to identify potential areas of unacceptable care in nursing homes. HCFA will eventually use this data to assess nursing home performance in such areas as avoidable bed sores, loss of mobility, weight loss and use of restraints. This assessment will help HCFA and state surveyors better identify nursing homes for immediate onsite inspections, detect and correct systematic problems early, and ultimately help nursing homes improve quality.

New Legislative Proposals

In addition to the administrative steps described above, the Administration will ask Congress to help improve nursing home care and safety in four ways:

- **Immediate Penalties.** Ask Congress for the authority to impose civil monetary penalties for each instance of serious or chronic violation. Until now penalties have been linked only to the number of days a facility was out of compliance with regulations.

- **Criminal Background Checks.** Ask Congress to establish a national registry of nursing home employees convicted of abusing residents and to require nursing homes to conduct criminal background checks on all potential personnel.
- **Nutrition and Hydration Therapy.** Ask Congress to allow more types of nursing home employees, with proper training, to perform crucial nutrition and hydration functions.
- **Nursing Home Ombudsman Program.** Ask Congress to reauthorize a strong nursing home ombudsman program through the U.S. Administration on Aging. Ombudsmen are an excellent source of information about poor-quality nursing homes and abuse or neglect of patients.

Public vs. Private Accreditation

Finally, at Congress' request, the HCFA report also evaluated whether private accreditation of nursing homes would be preferable to the current system of public accreditation. HCFA secured an independent evaluation by Abt Associates, to assist in preparation of that portion of the report. The report concludes that the private Joint Commission on Accreditation of Healthcare Organizations (JCAHO)'s survey process was not effective in protecting the health and safety of nursing home residents. According to Abt Associates, granting "deeming" authority to JCAHO would place nursing home residents at serious risk. For example, in more than half of 179 cases where both HCFA and JCAHO conducted inspections of the same nursing homes, JCAHO failed to detect serious problems identified by HCFA.

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CLOSE HOLD



DEPARTMENT OF HEALTH & HUMAN SERVICES

Nursing Home Quality
Health Care Financing Administration
File

JUN 3 1998

The Administrator
Washington, D.C. 20201

DRAFT

Note To: Kevin Thurm
Deputy Secretary

Subject: Nursing Home Enforcement Initiative

When we met on December 15 regarding nutrition in nursing homes and enforcement issues, you asked that we convene a group of people from the Department to discuss HCFA's plan and how they could help us. Our meeting in late January with the Department staff was a positive one. We discussed their comments to our strategy paper as well as other suggestions HCFA could include. Representatives from ASPE, ASL, ASMB, OIG and OGC participated. A copy of the revised paper and time table are attached.

As you know, I have also met with a large group of consumer and nursing home advocate groups, as well as with industry representatives. I think we need to move forward with our initiative to improve enforcement. In addition, a series of other things related to nursing homes have arisen which will require some response on our part within the next year. These include the three studies, one report to congress, and a potential congressional hearing.

HCFA Report to Congress on Feasibility of Deeming and Evaluation of the Nursing Home Survey and Enforcement Process.

Currently under HCFA internal review is a comprehensive Report to Congress on the feasibility of deeming in nursing homes and evaluating the effectiveness of the nursing home survey and enforcement process. Except for the issue of deeming, our proposed strategic plan addresses many of the issues addressed in our Report to Congress.

Other Studies

Government Accounting Office (GAO) - The GAO is conducting two studies related to nursing homes. The first is a study of deaths in California purported to have occurred as a result of poor nutrition and dehydration. GAO expects a preliminary report in late summer. The second is a study of the nursing home enforcement process. GAO has included the States of Michigan, Texas, California, and Pennsylvania in their study. From some of the questions asked by GAO, we surmise that the issue of Federal oversight will be one of study's findings. While our strategic plan touches on Federal/State operations, we are also considering changes to HCFA's Federal oversight functions on a separate track.

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Special Senate Committee on Aging - HCFA staff has also been involved in a couple of meetings with staff from the Special Senate Committee on Aging. Early indications are that they expect to hold a hearing on the Omnibus Budget Reconciliation Act of 1987 (OBRA'87) survey and enforcement program sometime this summer.

National Senior Citizens Law Center - A paper prepared by the National Senior Law Center and funded by the Commonwealth Fund, entitled "What Happened to Enforcement" is a precursor to a study now being conducted in Michigan, Georgia, New York, Texas & Washington. Although a release date for the study has not been set, we expect the study to criticize the level of citing deficiencies and enforcement actions.

Other Issues

Reducing Medicaid Participation - A Florida facility which is part of the 331-home Vencor nursing home chain was fined \$360,000 for inappropriately discharging Medicaid beneficiaries. Withdrawal from Medicaid does not appear to be a trend; however, current Federal law and regulations do not deny a facility's right to terminate its provider agreement or reduce the extent of its participation in Medicare and/or Medicaid. The change in extent of participation is allowed under the "distinct part" concept. The distinct part provision permits hospitals and other entities to have a part of their institution rendering skilled nursing services to be certified as a SNF, NF, or SNF/NF while recognizing that the entire institution (that provides a different type of care) should not be subject to the SNF/NF requirements. The current interpretation of the "distinct parts" provision allows that a portion of a nursing home may participate in Medicaid and/or Medicare while the rest does not. Federal regulations only require that a distinct part be physically distinguishable, such as a wing, corridor, floor, etc. The number of beds in distinct parts varies. Facilities change the size of their distinct parts by notifying the State, HCFA regional office, or fiscal intermediary.

While this issue is not addressed in our strategic plan, we are pursuing a regulatory fix to help close the loopholes for corporations maximizing profits at the expense of our poorest residents.

Roll Out

HCFA will have an ongoing roll out approach. A fact sheet or press release outlining the proposed strategies will be prepared. HCFA will work with Department staff to coordinate a roll out to five audiences: Congress, States, nursing home providers, consumer and advocacy groups, and the media. Roll out strategies could include an initial briefing for trade press, with a coordinated briefing for State, Congressional staff, and other selected stakeholders. Ongoing roll out activities will include a coordinated

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effort to aggressively communicate the strategy in a variety of settings, including presentations by HCFA staff at conferences and speech blocks to be incorporated into addresses given by the Secretary, the Administrator, and HCFA Senior Staff.

At this point I think it would be beneficial to convene another meeting, both to update you and our Department colleagues on our status, and to discuss our plan described above to roll out this initiative with consumers groups, States, and nursing home providers.


Nancy-Ann Min DeParle

Attachments

*Strategic Approach
for Improvements to the
Survey & Certification Program
for Nursing Homes*

Summary

Tackling patient abuse in nursing homes; improved targeting of poor performing facilities; heightening awareness of specific quality of life issues via the survey process; focusing on nutrition and hydration; quality of care issues; and developing new approaches for communicating with the nursing home industry are HCFA's short term strategies addressing current problems in nursing homes. HCFA's long range strategies include: implementing an integrated and comprehensive data system to assist in measurement and improvement of nursing home performance; establishing quality indicators; and developing analytical mechanisms for the optimal use of data.

Defining the Problem

For the past few years, HCFA has moved towards a framework for improving the quality of care delivered to beneficiaries through measurement and improvement interventions. This includes the survey and certification process and data design and collection functions for the myriad of providers and suppliers participating in the Medicare and Medicaid programs. This recent emphasis represents a significant shift away from an exclusive focus on reviewing provider compliance with established threshold requirements for Medicare/Medicaid participation.

HCFA's program strategy and quality vision are as sound with respect to nursing homes as for other provider types; however, external perceptions of this changed focus are working against us. The current HCFA emphasis on quality improvement suggests to some that our focus on data measures and quality improvement interventions would result in a reduction of on-site survey activity in nursing homes. Data collection and information dissemination ideally would make the survey process more efficient and allow surveyors to concentrate inspection activity where it will do the most good.

Despite ten years of significant advances in quality assurance and enforcement, we continue to be concerned about poor quality care in nursing homes. Although there has been considerable anecdotal attention to this issue in the national media, some of it overblown, we believe there is reason to believe things are not going in the way we intended. We also want to be proactive in addressing those concerns in the short run so that our longer-range strategies of implementing a data system and quality indicators will mean that nursing home performance is not derailed.

A. Enforcement Improvement Strategy

HCFA recommends the following short-term enforcement strategy that is multi-faceted and dynamic.

1. Patient Abuse

Allegations of patient or resident abuse have long been identified as an area of concern at both State and Federal levels. Moreover, prevention of abuse has been considered by various workgroups, including a Department level workgroup on elder abuse several years ago. Often these workgroups have a very broad agenda which inhibits their ability to develop usable solutions. From time to time, HCFA, Congress and various interest groups have reviewed the value of criminal background checks for nursing home employees and registries for abusers. Recently, some congressional staff have again raised these issues. Also, the law prevents States from issuing a civil money penalty for "each instance" of abuse, requiring instead that the penalty amount be linked to days out of compliance.

To reduce patient abuse in nursing homes, HCFA proposes to:

- ▶ *Prevent, identify and/or penalize patient abuse.* We will explore the value of criminal background checks and a national abuse registry. This effort will be coordinated with efforts in home health agencies on criminal background checks.
- ▶ *Focus on one or more types of abuse for national attention and correction in egregious cases (e.g. verbal or physical abuse; neglect, misappropriation of property)*
- ▶ *Propose civil money penalties for "each instance" of abuse, as an optional alternative for "every day out of compliance", when a civil money penalty is the remedy of choice.* (Requires a legislative change). This eventually would give States the flexibility to give a penalty on the spot without having to wait to see how many days a facility is out of compliance before computing and collecting fines.

2. *Targeting Poor Performers*

OBRA 87 permits imposing sanctions immediately on nursing homes. HCFA, as a matter of policy, imposes sanctions immediately on facilities defined as poor performers. These facilities, which are not allowed an opportunity to correct before the sanction is imposed, are facilities with a history of swinging between compliance and noncompliance. Over the past two years we've found that this definition does not encompass the very group we were attempting to define, i.e., those who have a history of providing poor or marginal care and/or chronically have serious compliance issues.

To assure that appropriate penalties are imposed, HCFA will:

- ▶ *Identify facilities with chronically poor compliance history and have States monitor these facilities more closely.*
- ▶ *Redefine the term "poor performers" in consultation with the various stakeholders, including imposing immediate sanctions on poorly run nursing home chains within a State.*

3. *Survey Process & Enforcement*

The OBRA 87 survey process and enforcement systems are complex and are especially difficult to apply to specific requirements for participation in the Medicare and Medicaid programs.

HCFA will continue to improve the survey process:

- ▶ *Identify quality of life/quality of care issues critical to quality nursing home care in consultation with consumer advocates.* Provide clearer guidance on a limited number of provisions that surveyors would focus on during every survey. We would not eliminate current survey requirements but would sharpen the focus on certain areas. (e.g. Admissions contracts, drug therapy)
- ▶ *Strengthen resident safety by applying the scope and severity guidance to current enforcement process for life safety code violations.*
- ▶ *Refine and prescribe HCFA's policy for following up on nursing homes who have corrected deficiencies.*
- ▶ *Pilot potential survey processes which could improve HCFA's ability to detect serious negative outcomes, particularly in nutrition and hydration.*

4. *State/Federal Operations*

Variation of State survey findings and enforcement actions is an issue frequently raised in relation to nursing homes. Consumer advocates and provider organizations have both raised concerns regarding inconsistencies among State and Federal surveyors. This variation applies to both differences in average number of deficiencies, and number and type of enforcement actions. One of the issues that GAO plans to study is inconsistencies among States. This is also an area of interest to the staff of the Senate Aging Committee.

HCFA will determine whether such variations reflect real differences or measurement error. Where it is found to be inconsistent measurement techniques, those problems will be addressed. Where we find significant variation, we will identify outlying States and/or Regions and implement strategies to improve performance.

- ▶ *Review existing evidence of State variation in enforcement and develop appropriate responses for explaining and/or reducing significant variation in State survey and enforcement activities.*
- ▶ *Develop legislative, regulatory or operational policies, as appropriate, to strengthen the effectiveness of Federal oversight of State operation of the survey and certification program.*
- ▶ *Implement enhanced strategy for Federal oversight for Federal Monitoring Surveys (FMS) and the State Agency Quality Improvement Program (SAQIP).*

5. *Communications*

In order to effectively pursue a coordinated agenda, HCFA will:

- ▶ *Continue to develop fact sheets, charts, talking points and speech blocks that summarize HCFA's more rigorous enforcement program. These will include examples of cases where HCFA actions have made a difference, describe the difference in standards now and in the past, and identify additional efforts planned.*
- ▶ *Aggressively communicate its strategy in meetings with consumer advocates, professional organizations, nursing home industry representatives, the states, Congress and the press. For optimum impact the administrator and other central office officials, as well as regional administrators should be integrally involved.*
- ▶ *Identify third parties, such as advocates and legislators, who endorse, formally or otherwise, HCFA's program.*
- ▶ *Link nursing home quality activities with the Administration's emphasis on volunteerism in America.*

B. *Focus on Nutrition and Hydration*

HCFA will continue to focus on the nutrition and hydration needs of residents. The following outlines activities currently in progress and additional steps we propose to ensure that the nutrition and hydration needs of residents are met.

1. *Changes to Requirements*

Develop policy and or a legislative proposal to allow for an increase in the type of nursing home staff available to participate in the feeding of residents. Currently only licensed health professionals, nurse aides, or volunteers are allowed to help feed residents; administrative staff are not allowed to help food residents.

2. *Surveyor Training - focus on nutrition and hydration in current and proposed training*
Increase expertise of surveyors and nursing facilities on the maintenance of proper nutrition and hydration of residents. This will include intensified training as well as improved survey protocols.
3. *Nutrition Quality Initiative*
Develop a repository of best practice guidelines for caring for residents at risk of weight loss and dehydration in cooperation with the Administration on Aging, American Dietitians Association, industry, consumers and professional groups through Sharing Innovations in Quality and any other available venues.

C. Measurement/Improvement Infrastructure Strategy

1. In July, 1998, HCFA will begin collecting MDS data from nursing homes at both the State and national levels. This is the first step in a major HCFA initiative to use MDS data to improve the quality and cost effectiveness of nursing home services. Over the long term this system will:
 - provide data that will enable State survey agencies to enhance on-site inspections, and monitor facility performances on an ongoing basis;
 - provide information to support provider quality improvement activities,
 - provide information for beneficiaries and their families to use when making health care choices;
 - furnish data necessary for developing and implementing case-mix based prospective payment systems for both Medicare and Medicaid;
 - facilitate the development of clinical "best practices", and coverage policy
2. As part of its longer term strategy for nursing home improvement, HCFA should:
 - Fully implement the MDS data collection and analysis system at both the State and national levels. This should include connectivity with other systems for Medicare and Medicaid claims and for the PRO data.
 - Develop, test and implement protocols for assuring the validity of MDS data collected at the State and national levels. This should include both a plausibility analysis of the collected data as well as onsite audit processes.
 - Develop, test and implement quality indicators for use in analyzing MDS. Quality indicators and related performance standards will provide information on a facility's performance on one or more domains of care as compared to the standard or other providers.
 - Launch in conjunction with State survey agencies an effort to develop, implement and evaluate demonstration projects that will allow for testing innovations for quality oversight and improvements. These projects would be carried out with, not in lieu of, the nursing home survey process. It is only when we can demonstrate and prove that our arsenal of new tools actually result in quality improvement above the current enforcement level in nursing homes can we actually begin to sensibly focus on the locations, scope and duration of on-site visits.
3. Even though the system infrastructure is currently being installed, a great deal more work is required before the MDS data can be effectively utilized as part of a reengineered survey and certification program for nursing homes. Prior to relying on MDS data in lieu of other forms of evidence gathering, we must have in

place methods for assuring its accuracy and usefulness. In addition, a capability to analyze the collected data for indicators and standards of performance quality is critical to its use for measurement and improvement. It will also be necessary to establish protocols for integrating the use of MDS data into an improvement system for nursing homes and an enforcement process that fulfills HCFA's responsibilities under the survey and certification program.

Enforcement/Nutrition Initiatives Timeline								
Task	98 Summer	Fall	99 Winter	Spring	Summer	Fall	00 Winter	Spring
1. <i>Legislative Proposal to Permit Civil Money Penalties for "each instance" or "each day of noncompliance"</i> Draft language	x							
Once legislation becomes law - draft implementing instructions.		90 days after law						
Incorporate concept into training for State survey agencies			120 days after law					
2. Targeting Poor Performers Develop list of "bottom of the barrel" providers in each State using various indicators.	x							
Develop monitoring strategy for HCFA and States to more closely monitor facilities with chronically poor compliance histories.		x						
Based on Report to Congress and GAO reports distill other recommendations/strategies into monitoring strategy		x						
Work with States to implement monitoring strategy		Ongoing	-----	-----	-----	-----	-----	Ongoing
3. Survey Process & Enforcement <i>Enhance surveyor training</i> Improve basic health facility surveyor training course to emphasize decision-making, investigation techniques and documentation			x					
Develop & conduct training course for State surveyor supervisors to assure greater consistency			x					

Enforcement/Nutrition Initiatives Timeline								
Task	98 Summer	Fall	99 Winter	Spring	Summer	Fall	(01) Winter	Spring
	<ul style="list-style-type: none"> Aggressively communicate HCFA strategy in meetings with consumer advocates, professional organizations, nursing home industry representatives, States, Congress and the press. 	Ongoing	-----	-----	-----	-----	-----	-----
<ul style="list-style-type: none"> Determine feasibility of linking our efforts with Volunteer organizations regarding nursing home initiatives 	X							
B. FOCUS ON NUTRITION/HYDRATION								
1. Changes to Requirements <ul style="list-style-type: none"> Feeding residents Develop guidance to States to better use volunteers in the feeding of residents. 	X							
<ul style="list-style-type: none"> Require special training for individuals to feed residents who have swallowing or other feeding problems (law) 		X						
<ul style="list-style-type: none"> Permit individuals paid by the facility who do not have nurse training or nurse aide training to feed residents as long as they've either had special training or food residents who do not have a feeding problem. (Program memorandum, State Operations Instructions) 		X						
<ul style="list-style-type: none"> Develop legislative proposal which would be self-implementing to require individuals to have training in feeding residents. 	X	X						
2. Nutrition Summit <ul style="list-style-type: none"> Identify stakeholders and individuals who have expertise in this area; develop contract to convene summit. 	X							
<ul style="list-style-type: none"> Hold Summit (will look at draft interpretive guidance & make other suggestions methods to improve nutrition and hydration in nursing homes) 			X					

Enforcement/Nutrition Initiatives Timeline								
Task	98 Summer	Fall	99 Winter	Spring	Summer	Fall	00 Winter	Spring
Make revisions to policy based on Nutrition Summit & prepare in final.				x				
3. Satellite Presentation & Educational Materials Contract with entity to present satellite training and assist in the development of educational material.					x			
C. MEASUREMENT/IMPROVEMENT INFRASTRUCTURE STRATEGY								
1 Collect Minimum Data Set (MDS) data from States.	x							
2. Explore methods to analyze MDS data for accuracy and usefulness. Also analyze data for indicators and standards of performance			x					
3. Assure that MDS data collection and analysis system are connected to other systems for Medicare and Medicaid claims & PRO data.					x			
4. Develop, test and implement quality indicators for use in analyzing MDS data collected at State & National level.					x			
5. With States, develop implement and evaluate demonstration projects that will allow for testing innovations for quality oversight and improvements.						x		

1. Proposed legislation in House bill is regs to be enacted not more than 60 days after statute's enactment and for the Senate legislation -- not more than 6 months after enactment. These timeframes are unrealistic as HCFA's regulation process historically takes a minimum of 2 years.

2. Expertise needed for this area. Contract with NCCNHR or other organization to convene summit. Contract S may be needed for this activity.

3. Contract S may be needed for this activity.

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File Nursing Home



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Washington D.C. 20201 - 0001

Quality

NOV. 3, 1997

TO SARAH BIANCHI

FROM CHRIS PEACOCK / 202-690-6149

FAX: 456-7431

2 PAGES TO FOLLOW

NURSING HOME ENFORCEMENT TALK POINTS 10/29/97

1) WE IMPLEMENTED THE TOUGHEST NURSING HOME REGULATIONS EVER DESPITE STRONG OBJECTIONS BY INDUSTRY AND MANY IN CONGRESS.

We recognized that there were serious problems in regulation of nursing homes. That's why we initiated a thorough effort to establish tough new regulations that we implemented in July of 1995. Since passage of these regulations we have been cracking down and holding nursing homes to these tough new standards.

Many homes are being cited for problems that before were not cited. Under the new system, at one point 76 percent of providers were out of compliance.

2) MOST NURSING HOMES FIX PROBLEMS AS SOON AS THEY ARE FOUND.

Under the new regulations, when a problem is found, a facility must prepare a written plan of how they will correct it, and surveyors schedule a re-visit to verify that the problem is fixed.

Nearly nine out of ten homes cited for problems that could harm residents fix these problems right away.

Of 9863 homes found to have "level D deficiencies (defined as a situation that could cause harm, such as a loose floor molding) or above" between July of 1996 and August of 1997, 8571 had fixed the problem before inspectors returned.

3) FINES AND PENALTIES ARE NOT INTENDED TO BE WIDELY USED.

They are applied only if a home does not correct problems found by state inspectors in a timely fashion.

The new regulations do allow for immediate action, with no opportunity for correction, if a facility is providing care that is a serious threat to the resident's well being.

But for other problems, enforcement is aimed at education about what is expected and how to improve care, and then verifying that problems have been fixed and that care is improving. That is a reasonable approach, given how much tougher the new regulations are than the old ones.

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L.A. Times; 10-23-97

22,000 Needless Nursing Home Deaths Alleged

Seniors: U.S. auditors are probing lawyer's claim based on study of records in state from 1986 to 1993. Industry officials challenge research method.

By LEE ROMNEY and JULIE MARQUIS
TIMES STAFF WRITERS

Federal auditors are investigating a claim that nearly 22,000 nursing home patients in California died from preventable conditions such as malnutrition, dehydration and urinary tract infections between 1986 and 1993, federal and state officials said Wednesday.

Investigators for the General Accounting Office arrived in California last week to begin looking into a voluminous complaint from a Palo Alto attorney who based his findings on a review of 300,000 death certificates.

In a letter to the GAO this month, Sen. Charles E. Grassley (R-Iowa), chairman of the Senate's Special Committee on Aging, asked the GAO to investigate information gathered by attorney Von Packard.

The GAO investigators visited nursing homes, began reviewing medical records and met with state health officials. They also interviewed Packard and returned to Washington with his list of 21,680 nursing home patients who died of what Packard considered questionable causes between 1986 and 1993, as well as a sampling of 1993 death certificates, Packard said.

Packard approached the Senate committee last summer with his data, which Grassley found "very disturbing," said a Senate committee spokesman, who asked not to be identified. Grassley then contacted the General Accounting Office and after five weeks of discussion requested a formal investigation on Oct. 1.

Nursing home industry officials reacted angrily Wednesday, accusing Packard of seeking "free advertising" and of mimicking aggressive legal challenges to nursing homes in Florida and Pennsylvania. They said the lawyer's method of examining death certificates was not a sound way to assess the quality of care.

"The study is just fraught with big holes," said Lori Costa, director of regulatory programs for the California Assn. of Health Facilities, which represents 1,500

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Continued from B1
long-term care facilities in the state. "A cause of death has to be proven by autopsy."

Grassley has asked the GAO to "independently verify" the prevalence of malnutrition, dehydration, sepsis, fractures, burns and scalding in California nursing homes, according to the letter from Grassley to the GAO.

"Because of the seriousness of this request and the potential life-threatening implications of its subject matter, the committee respectfully requests that the GAO address this request immediately," the letter said.

If the claims appear to be valid, then Senate hearings on the matter are likely, the spokesman said.

California health officials said they are cooperating with the GAO and, for now, expect a review of only three Northern California facilities. The state health department, which inspects homes for the federal government, is not the target of the probe, said Brenda Klutz, deputy director of state licensing.

Klutz said she was unaware of Packard's review until recently. But in general, a finding of malnutrition or dehydration on a death certificate, without evidence of an underlying condition such as cancer, would "raise a red flag," she said.

"I would want to investigate further," she said.

A UCLA epidemiologist agreed that it would be a mistake to rely on death certificates alone for anything other than general surveillance—unless the cause of death was some kind of accident.

'Because of the seriousness of this request and the potential life-threatening implications of its subject matter, the committee respectfully requests that the GAO address this request immediately.'

SEN. CHARLES E. GRASSLEY (R-Iowa)
Chairman of the Senate's Special Committee on Aging

"It may be the only way to get cheap data, but it should be interpreted with caution," said Beate Ritz of the UCLA School of Public

Health.
The GAO's findings in California will be used to determine whether there is a national crisis of preventable deaths in nursing homes, the Grassley committee spokesman said.

Grassley's office is also looking into whether the federal Health Care Financing Administration is doing an adequate job of disciplining nursing homes where violations of federal nursing home rules are reported.

The committee spokesman said Grassley is concerned about a seemingly low percentage of nursing homes in violation of the law that are actually fined or otherwise penalized by federal regulators.

Time magazine reported Monday that only 2% of nearly 10,000 nursing homes with significant deficiencies were fined or penalized.

The U.S. health agency's officials said Wednesday that fines and penalties are not intended to be widely used, but rather are applied only if a home does not adequately correct its problems. The low penalty rate reflects the fact that most homes fixed their deficiencies, said health agency spokesman Chris Peabody.

Packard's investigators began reviewing death certificates after meeting Ila Swan, a 57-year-old Vacaville woman who launched her own review of county death records after witnessing what she considered disturbing conditions at a home where her mother was a patient. Packard said his investigators are now launching death certificate reviews in four or five other states, but declined to name them. He began his California probe about a year ago.

Packard said he looked at the records of those who died of one or more of the following: malnutrition, dehydration, bed sores, urinary tract infections and bowel obstructions. He removed anybody from the list who had another diagnosis, such as cancer, that would have contributed to malnutrition. Of those who died of dehydration, he removed all those with Alzheimer's disease, which often prevents swallowing in its advanced stages, he said.

"This is very understated," he said of his data. "There is a widespread pattern of severe neglect."

Based in part on Packard's findings, the Senate committee is also looking at the overall risk of malnutrition in nursing homes.

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American Health Care Association

1201 L Street, NW, Washington, DC 20005-4014

FAX: 202-842-3860

Writer's Telephone: 202/898-2858

*File Nursing
Loren
(Chris Files)*

April 22, 1997

Mr. Chris Jennings
Old Executive Office Bldg
Room 212
Washington, D.C. 20500

Dear Chris:

We oppose the \$2.9 billion in added reductions toward skilled nursing facilities (SNFs) proposed by the Administration. We are also disturbed by the Administration's efforts to reduce Medicaid spending on long term care by \$5.5 billion.

Throughout the balanced budget debate, we have supported the Administration's efforts to develop a prospective payment system (PPS) for SNFs. In addition, we did not oppose your original proposal of \$7 billion in reductions for SNFs. We were concerned when the Administration came forward with an additional \$700 million in cuts to SNFs. But now we are shocked and dismayed by the Administration, once again, attempting to impose further reductions on certain providers. An additional \$2.9 billion in reductions from SNFs is disproportionately unfair when compared to other providers.

This does not include your estimates of \$1.7 billion in additional reductions from salary equivalency regulations proposed on 3/29/97. These new proposals will threaten SNFs' ability to provide quality care, let alone achieve the highest practicable level of quality care. We have worked closely with you to meet our savings target. The SNF industry should not be punished because others were unable to meet their targets. We urge you to consider alternative options to achieve your savings -- options that are fair and options that don't threaten quality. We would gladly work with you in developing these.

We also oppose the Administration's per capita cap proposal to find additional savings for Medicaid in long term care. Capping growth at 5.5% annually, while CBO predicts an 8.2% increase per year, will hamper our ability to provide the level of quality that is expected of us. As you know, the reduced baseline growth estimate will already achieve an \$86 billion savings from Medicaid over the next 5 years.

We have also heard that the Administration has increased its proposed net savings from Medicaid from \$9 billion to \$25 billion. If you are putting \$13 billion back into the program for children and legal immigrants, your proposal actually equates to a \$5.5

Chris Jennings
April 22, 1997

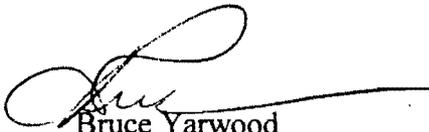
billion cut from long term care. The impact on the typical 120 bed facility would equate to a loss of \$300,000 over five years.

This hit hurts especially when you couple it with the repeal of the Boren Amendment. In addition, more than two-thirds of the residents in nursing facilities are dependent on Medicaid, and the program is already underfunded. If 20% of the patients in a hospital are Medicaid dependent, the hospital receives disproportionate share (DSH) payments. More than 66% of the residents in nursing facilities are Medicaid dependent and those facilities receive no DSH payments!

Per capita caps, repealing the Boren amendment, and cutting \$25 billion from the Medicaid program is not an effective way to promote and achieve quality.

Chris, we need your help. We need the Administration to move back toward its original \$7 billion savings for SNFs that we agreed to earlier this year and to allocate reductions more fairly. We also urge you to revisit your Medicaid proposal and stand up for the link between quality and funding.

Sincerely,



Bruce Yarwood
Legislative Counsel

enclosure(s)

ADMINISTRATION'S LATEST MEDICARE OFFER

CRIPPLING AND UNFAIR TO SKILLED NURSING FACILITIES

April 22, 1997

SNF PROPOSALS - 5 YEAR ESTIMATES

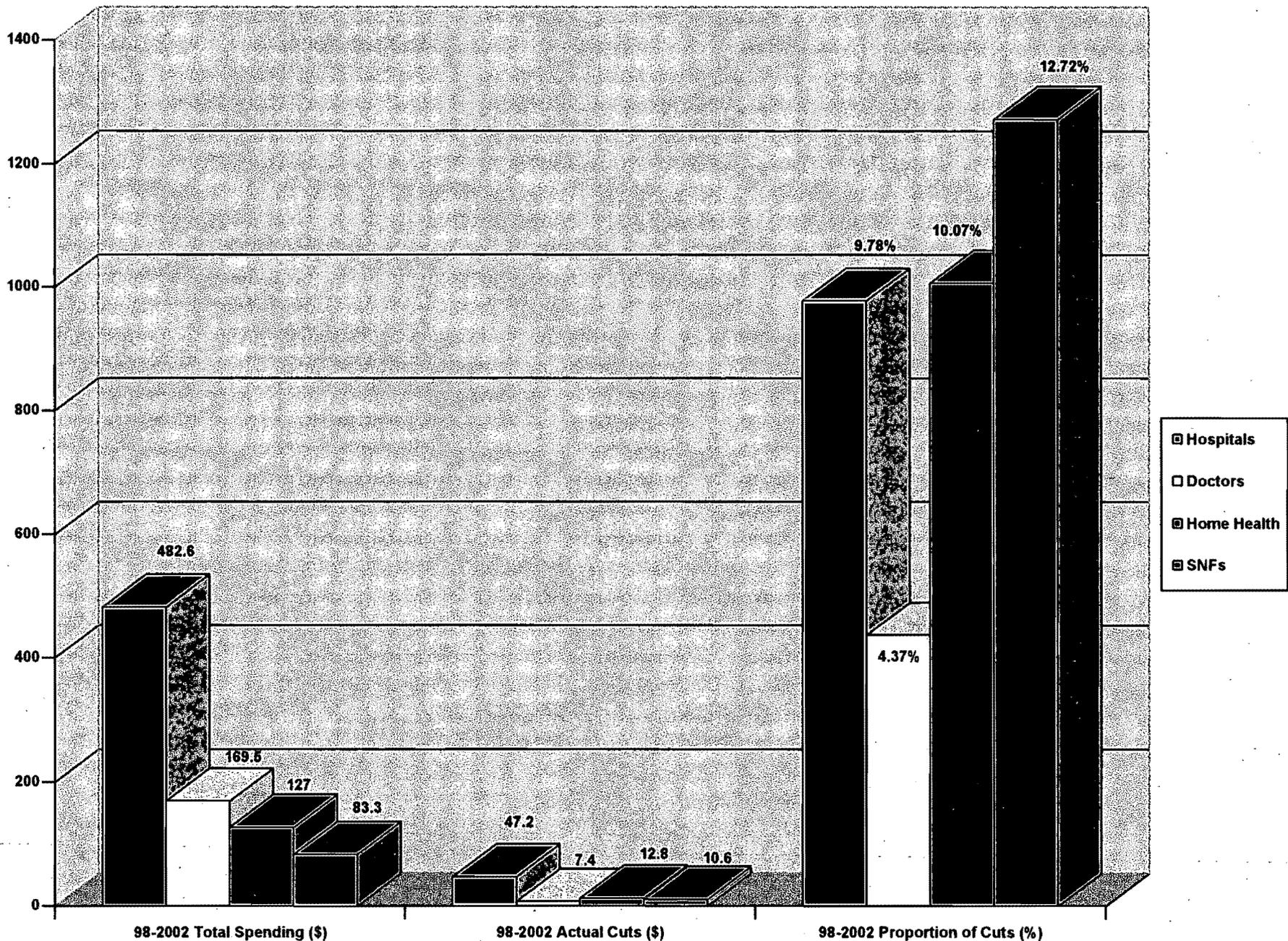
ORIGINAL WHITE HOUSE BUDGET		\$ 7.0 Billion
MARCH 3, 1997 CBO SCORING	+ 700 Million	\$ 7.7 Billion
MARCH 28, 1997 SALARY EQUIVALENCY REGULATIONS	+ 1.9 Billion	\$ 9.6 Billion
APRIL 8, 1997 WHITE HOUSE OFFER	+ 2.9 Billion	\$12.5 Billion
GOP BALANCED BUDGET ACT OF 1995 - FINAL <u>6-YEAR OFFER</u>		\$ 9.6 Billion

CBO SCORING OF FY '98 BUDGET PROPOSAL - MARCH 3, 1997 AND LATEST \$18 BILLION OFFER

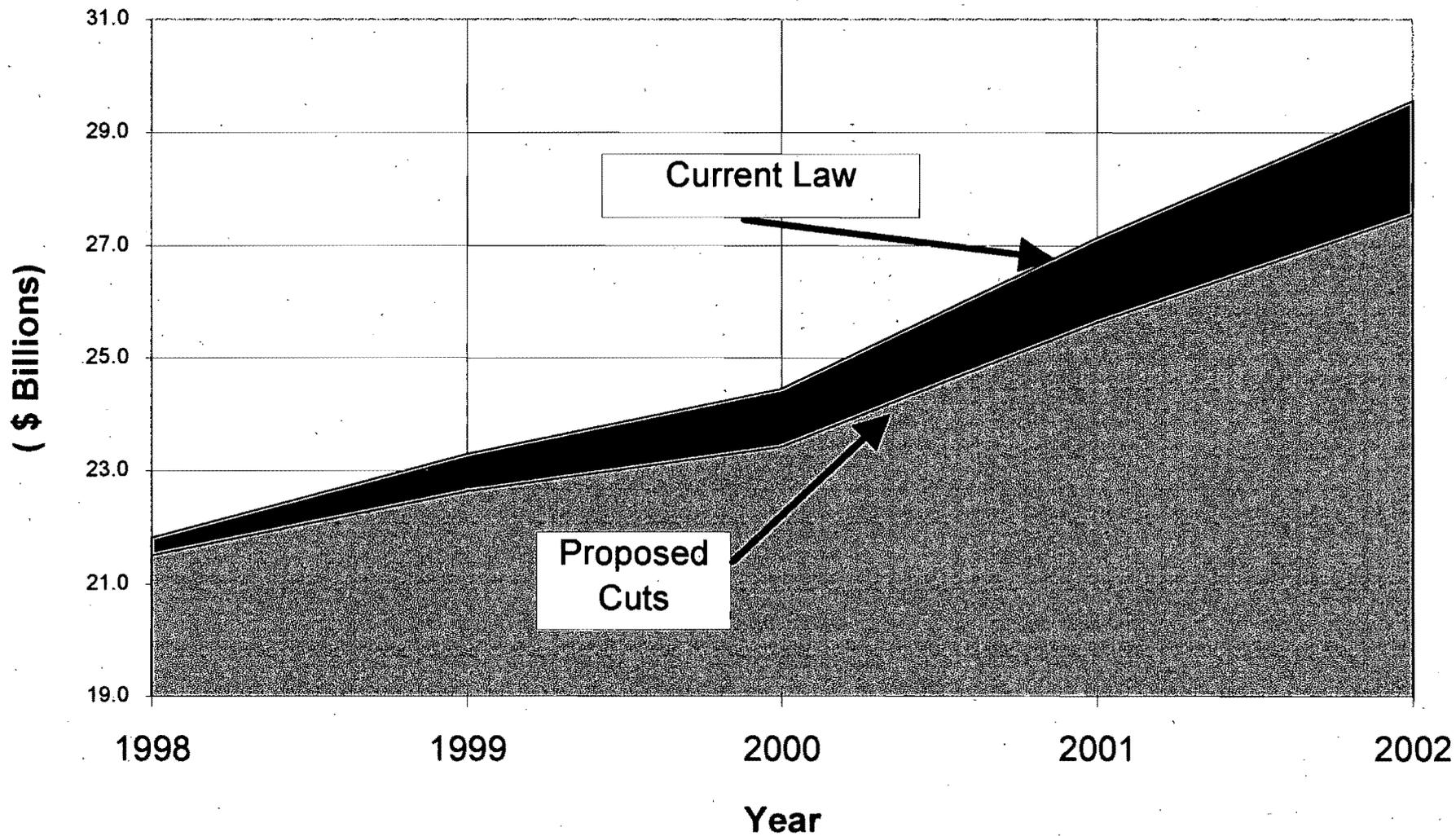
	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	'98-02	'98-07
Skilled Nursing Facilities PPS	-0.1	-1.3	-1.8	-2.1	-2.4	-2.7	-3.0	-3.3	-3.7	-4.1	-7.7	-24.5
Including 3/29 REGs.	-0.0	-0.5	-0.6	-0.6	-0.2	-0.6	-0.6	-0.6	-0.6	-0.6	-1.9	-4.3
Including 4/8 Offer	-0.3	-0.5	-0.6	-0.7	-0.8	-0.8	-0.8	-0.8	-0.8	-0.8	-2.9	-6.9
SUBTOTAL	-0.4	-2.3	-3.0	-3.4	-3.4	-5.1	-5.4	-5.7	-6.1	-6.5	-12.5	-35.7

DISPROPORTIONATE IMPACT ON SKILLED NURSING FACILITIES

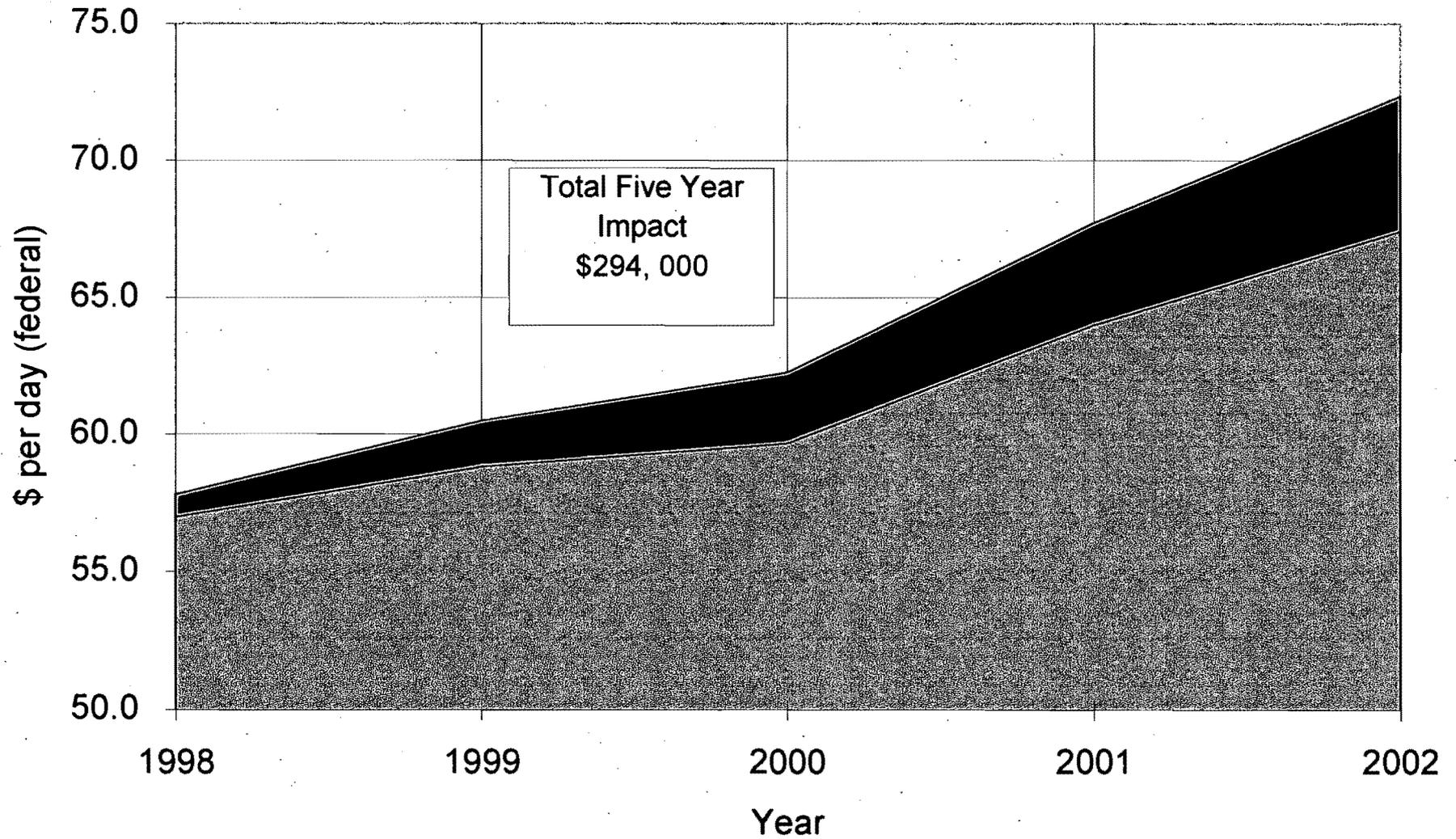
[Based on CBO Projections - In Billions - Proportional Estimate Not Shown in Dollars but in % of Total Five-year Spending]



Impact of \$25 Billion Medicaid Cut on Nursing Facilities



Typical Facility Impact of \$25 Billion Medicaid Cuts (Federal Share)



Nursing Home Quality Act

Comparison of Administration and Grassley Bills on Nursing home Staffing Grants - 10/2

-- Findings -- The Grassley Bill has a section that lists the findings from the HCFA staffing report to Congress. The findings note that the 2 hour level is not a standard for appropriate care and that the 2.9 hour level is probably understated.

-- Completion of Phase 2 of Staffing Report - The Grassley bill has a section that requires the Secretary to provide the final portion of our report to Congress by 7/1/01. This is consistent with the President's announcement.

-- Report on Minimum Staffing Levels - The Grassley bill requires the Secretary to publish a NPRM 6 months after the final report is sent to Congress. This NPRM must make recommendations on the appropriate minimum staffing levels. A final rule is required 6 months after the NPRM. This is generally consistent with the President's announcement.

-- Grants -- The Grassley bill includes a \$1 B grant program very similar to the Administration's bill with the following exceptions:

- * The 25/75 division of States into priority categories is eliminated completely so that all State could apply of these grants on an equal basis. This is to avoid using 2 hours as a standard.
- * The grants would be \$500M available for only 2 years instead of \$200M ^{each of} over 5 years. \$1 billion
- * Uses of funds section adds improvement to workplace safety and nursing facility management and removes nursing facility bonuses in order to focus only on staffing levels.
- * A new provision is added that prohibits use of funds for activities that would not be consistent with current law. This provision would prohibit the use of staff with fewer than 75 hours in CNA training.
- * A new provision is added that prohibits funds that would support publicly owned or operated nursing homes. This is to address UPL concerns.
- * A new provision is added that prohibits "supplantation" of existing activities.

-- CMPs -- The immediate collection of Civil Monetary Penalty (CMP) provision is eliminated in the Grassley bill.

-- Nurse Aide Training -- The Grassley Bill includes a provision that increases the 75 hour nurse aide training level to 160 hours.

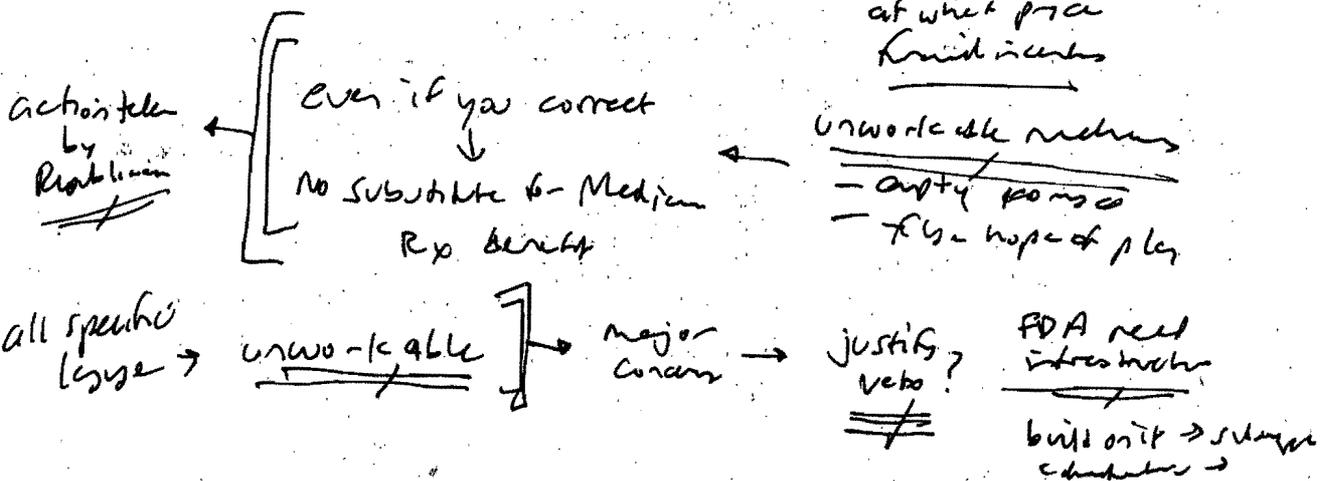
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New Nursing Home Staffing Initiative

Grants to the States

The Administration proposes to establish new incentive grants to states that commit to raising their staffing levels in nursing homes. States will compete for these grants and have flexibility in creating plans to increase staffing levels. The goal of these grants is to test innovative ways to increase staff levels, reduce turnover and ultimately improve quality of care in nursing facilities. States could use these grants:

- to enhance facility staff recruitment and retention efforts;
- to accelerate physical plant upgrades necessary to ensure patient safety or improve quality of life;
- for the education and training of nursing staff;
- to establish career ladders for CNAs;
- to convert outdated nursing homes to assisted living facilities; and
- for other nursing home staffing initiatives approved by the Secretary.

States could use also these funds to reward facilities meeting certain quality standards, such as the IOM recommended staffing levels for registered nurses or an absence of serious quality violations for a period of years.

Grant Funding Level-- The Administration will seek appropriations of \$1 billion over five years for these grants (*Will this be a mandatory Medicaid grant or discretionary funding through a multi-year account in HCFA or HRSA?*). The Administration would also use funds collected by the federal government from civil monetary penalties (CMPs) imposed on nursing homes to augment these grants. (*Does HCFA have an estimate of these collections and of the percentage actually retained to the Federal Government?-HCFA is still checking*)

Distribution of Funds-- Grant funding will be divided into two pools:

- Seventy-five percent (75%) of the funds will be used for states whose current nurse aide staffing levels are below two (2) nurse aide hours per resident day. These states will be required to provide assurances that they will raise their current staffing levels to the recommended level in order to receive funding.
- Twenty-five percent (25%) of the funds will be used for states who are above the recommended level. These states will still be expected to use their funds to further increase staffing and improve quality.

This level was chosen based on HCFA's analysis in Phase One of its report to Congress on *Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes*, July, 2000, which suggested that two nurse aide hours per resident day was the minimum staffing level necessary to reduce the likelihood of quality problems in a nursing home.

The Department will require states receiving funds to submit annual progress reports on staffing issues, which HHS will use to monitor state compliance with program guidelines.

New Requirements

Enhanced Reporting Requirements -- As a Condition of Participation for Medicaid or Medicare, nursing homes (or certified portions) will be required to provide detailed reports to HCFA on all nursing staff, including the total number of hours, the coverage per shift, whether the staff were CNAs, LPNs or RNs, and the average wage rate for each class of employees. Nursing homes will also be required to classify all residents in certified facilities into Medicare Resource Utilization Groups (RUGs) so that the severity of the facilities case-mix could be determined in a uniform manner. Similar to Rep. Stark's bill, the new reporting requirement would be included as part of the BBA giveback proposal to provide SNFs the full market basket update. These data will be used to update HCFA's nursing home compare web site.

National Minimum Staffing Requirements -- Based on findings and recommendations from Phase Two of HCFA's report on *Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes*, the Secretary will commit to develop and publish regulations on standards for minimum staffing levels in nursing homes, and will review federal reimbursements necessary to achieve these standards.

Civil Monetary Penalties -- Currently the federal government collects a small percentage of the revenue from CMPs assessed against nursing homes (States collect the remainder). These funds return to the Medicare Trust Funds. By statute, if a nursing home appeals a CMP, the federal government does not collect the penalty until after the appeal is settled. The Administration proposes two legislative changes to CMPs. The first will require that CMPs be withheld from future payments to the nursing home immediately following the imposition of a fine. In the event that a nursing home won its appeal, the federal government would return the funds with interest. Second, funds from these CMPs would be used for the new incentive grants to States, rather than returned to the Medicare Trust Funds.

↓
Cohen Letter

Study of Private Accreditation (Deeming) of Nursing Homes, Regulatory Incentives and Non-Regulatory Initiatives, and Effectiveness of the Survey and Certification System

EXECUTIVE SUMMARY

Background - Federal Responsibility

In 1996, about 1.6 million people received care in approximately 16,800 nursing homes across the United States. As the largest single payer for this care, the Federal government is responsible for ensuring: (1) that the health and safety of one of the nation's most vulnerable populations are protected; and (2) that expenditures are prudent. Nursing home care has improved compared to the poor conditions dramatized in scandals during the 1950s and 1960s. In spite of this improvement, some experts and the public continue to feel that the typical nursing home is terrible. Ongoing press reports of questionable practices reinforce a widespread negative perception of the quality of nursing home care and underscore the importance of the Federal government's responsibilities.

The Report's Purpose

The 1996 Appropriations Act required a study and Report to Congress on:

- Private accreditation and deemed status;
- Regulatory and non-regulatory incentives to improve nursing home care; and
- Effectiveness of the current system of survey and certification of nursing homes.

The study's key objective is to assess the effectiveness of the three broad mechanisms identified in the legislation -- private accreditation, incentives, and survey and certification. Limited time and resources have precluded attention to some related topics: current survey and certification resource issues; the introduction of user fees to generate needed revenue; privatization of the survey and certification function; sources of State differences in enforcement; and nursing home staffing issues. This report has focused on the analysis of problems with respect to the Federal nursing home survey and certification system. Although a thorough discussion of possible solutions to redress these problems is beyond the scope of the report, the Department of Health and Human Services is in the process of identifying improvements to the current system.

Methods

In late November 1996, we secured an independent evaluation contractor, Abt Associates, to assist us in conducting this study. Preliminary study plans were developed and shared with very

broad constituencies from whom we sought input. In general, all the groups we met with supported the outlined study approach. The study results follow.

Findings

Private Accreditation (Deeming) of Nursing Homes

Should nursing homes be offered a choice between the traditional State survey process and private accreditation to demonstrate their compliance with Medicare's nursing home requirements for participation?

Discussion

Proponents of private accreditation/deeming argue that:

- The current survey and certification process is punitive and inflexible, with inconsistent implementation and enforcement.
- Most nursing homes strive to provide good quality care, and succeed.
- The Joint Commission on Accrediting Healthcare Organizations (JCAHO), an organization that accredits nursing homes, is more efficient than HCFA because it primarily relies on facility administrators and clinical staff to enforce standards and it relies on industry expertise to set and revise standards.
- If some nursing homes choose accreditation to demonstrate compliance, States can then focus their resources on substandard nursing homes.

In contrast, opponents of private accreditation/deeming agree that the current system does not work as well as it should; however, they argue that:

- The current system should be improved, not scrapped.
- For the most part, nursing homes are not managed by "professionals."
- The average facility has a high level of compliance problems. There is a need for direct government monitoring and enforcement.
- Accreditation does not "work" in other contexts, even hospitals.
- There is an inherent conflict of interest because facilities pay the accrediting organization for the accreditation survey.
- Accrediting bodies are not accountable to the public or to government.

A fundamental question is the appropriateness of allowing a private entity to perform an important public function. In some sense, Congress has already decided the “appropriateness” issue with respect to skilled nursing facilities (SNFs) by granting the Secretary “discretion” to grant deemed status provided that accreditation offers a reasonable assurance that Medicare conditions of participation or, for SNFs, requirements, are met. In another sense, probably due to the concerns expressed by deeming’s opponents, Congress has circumscribed the “appropriateness” issue by exempting SNFs from those accredited provider types for which the Secretary “must” accord deemed status if it is found that private accreditation demonstrates compliance with Medicare conditions of participation or requirements.

The primary issue to be addressed by this report, then, is not the “appropriateness” issue per se - a fundamental policy issue that is unlikely to be resolved in any report - but rather, the empirical issue of whether in fact private accreditation demonstrates compliance with Medicare’s requirements. Accordingly, empirical studies were conducted to determine whether what is currently the most likely organization to be granted deeming authority, JCAHO, has procedures and standards that would provide reasonable assurance of compliance with Medicare’s requirements. The current survey and certification system does not always guarantee such compliance; therefore, implicit in all the empirical studies described is a comparison between the JCAHO and HCFA’s surveys.

Conclusions - Deeming

JCAHO has higher minimum qualifications for surveyors, requiring a master’s degree and five years of long term care management experience. It would not be surprising, then, if JCAHO’s survey were more effective than HCFA’s. However, results of the empirical studies did not support this expectation:

- In terms of content, JCAHO would have to change several standards to provide reasonable assurance that Medicare requirements would be met.
- JCAHO standards are heavily weighted toward structure and process measures, while HCFA standards have a more resident-centered and outcome-oriented focus.
- In contrast to HCFA surveys, observed JCAHO surveys did not collect sufficient information to assure compliance with Medicare requirements. Generally, observations of resident care were not a priority.
- HCFA’s survey system is more stringent in defining steps to be taken to correct deficiencies.
- JCAHO surveyors seem to miss serious deficiencies that HCFA surveyors identify.
- Public access to JCAHO survey findings is severely limited.

Studies found that by authorizing deeming for nursing homes, Medicare may save \$2 million to nearly \$37 million annually, depending on assumptions about costs and on the percent of facilities that choose the accreditation option. However, given that the studies produced overwhelming evidence that the JCAHO surveyors often miss serious deficiencies, in some cases even apparently unjustified deaths, **the potential cost savings to deeming would not appear to justify the risk to the health and safety of the vulnerable nursing home population.**

The problems identified with the JCAHO survey do not necessarily apply to other potential accrediting organizations. Fragmentary evidence from the new Long-term Care Evaluation and Accreditation Program (LEAP), a competitor of JCAHO that began accrediting nursing homes in November 1997, suggests that their survey may be very different from JCAHO's. If future empirical studies produce convincing evidence that LEAP, other accrediting organizations, or a revised JCAHO survey meets all the criteria for comparability with the HCFA survey discussed in this report, then it might be time to revisit the issue of deeming.

Review of Research Linking Payment to Improved Resident Outcomes and Non-Regulatory Quality Improvement Initiatives

Review of Research Linking Payment to Improved Resident Outcomes

The possible use of incentives to improve quality of care and promote quality of life for nursing home residents has been discussed for many years. Incentives could take several forms, including public recognition and/or payments. Although superficially incentive payment is easily understood (incentive payment being a financial award above the standard rate of reimbursement for care, not a restructuring of the payment system in general or an overall increase in nursing home reimbursement rates), there is a troubling lack of agreement about practical implementation issues such as the basis for awarding incentive payments and a method for distribution. Critics also point out philosophical objections, the extreme technical difficulties of linking payment to outcomes, the question of funding, and the challenge of integrating an incentives system with current regulatory standards and payment structures.

Through discussion with researchers and regulators and a literature review, HCFA found past but no presently operating Medicaid incentives systems. Documentation and evaluation of States' efforts are lacking, and the impact that these interventions may have had on residents' quality of care and life cannot be determined. In past State systems, the award of the incentive typically did not depend on resident outcomes measurement. In contrast, an unusually strong outcomes-based research demonstration was implemented in 36 proprietary nursing facilities in the San Diego area from 1980 to 1983. A recent reanalysis of data from this demonstration found "... beneficial effects on access, quality, and cost of care." While this conclusion seems sound for this particular intervention conducted more than 15 years ago, it is important to recognize how the vast changes in nursing homes and their environments over the years could affect this conclusion

for any present-day application. Even advocates for the idea of incentive payment admit that there is no incentives system that could be pulled "off the shelf" and implemented quickly. *Hence, there is a general recognition that additional research/demonstrations conducted under current conditions would be necessary before incentive payment could be considered as a viable option.*

Review of Non-Regulatory Quality Improvement Initiatives

The long-term care industry has turned attention to the concept of total quality management, which includes the continuous quality improvement (CQI) model. With the development of outcomes-based quality of care indicators, a number of planned interventions have been undertaken by both private and government entities with the objective of improving nursing home quality, as measured by these indicators. Although some of these interventions are conducted in partnership with Federal or State entities, they essentially lie outside the traditional regulation; hence, our characterization of them as non-regulatory.

The Report discusses a wide variety of long-term care quality improvement initiatives. These kinds of non-regulatory initiatives with their emphasis upon CQI are viewed by the American Health Care Association, JCAHO, and others as important and effective mechanisms for nursing home quality assurance. Some argue that these initiatives can supplant some or a very large part of the normal survey process, as proposed by a South Dakota initiative. It has been argued that the role of the surveyor can be expanded to assist providers in their quality assurance efforts without compromising the traditional role of solely determining compliance with requirements. The State of Washington may provide an example of an expanded information transfer role through the activities performed by their Quality Assurance Nurses. As yet, we have no evaluation to judge the effectiveness of this effort.

Although many of these interventions are appealing with anecdotal reports of positive results, empirical evidence of their effectiveness is lacking. Some projects have no evaluation with none planned or have not gone beyond a good intention. For others, there is an evaluation component, but the data are not in. In the case of still others, there is an evaluation and some evidence is in, but it is weak - either weak because the evidence was mixed or the design was inherently weak.

In contrast to this lack of evidence, we identified two nursing home quality improvement interventions which were accompanied by reasonably strong evaluation designs. One project, an extremely labor intensive intervention to reduce incontinence, produced an impressive reduction in incontinence rates. Unfortunately, these gains were not sustained when the external research staff ceased providing feedback to the participating nursing homes. The other intervention, the Ohio Pressure Ulcer Prevention Initiative, incorporated elements thought essential to proponents of these initiatives and had a strong evaluation design. The evaluation resulted in conclusive evidence that the intervention was not effective. However, it should be noted that in spite of expectations of effectiveness on the part of the proponents of initiatives like the Ohio project, there are compelling reasons to regard these kinds of interventions as weak. It may be too

optimistic to view feedback data on performance alone, or even performance information together with educational "best practices" information, as sufficient to change actual care practices.

We have found little to no evidence to support a belief in the effectiveness of these initiatives *as they are normally implemented in nursing homes*. The absence of evidence supporting these particular interventions does not, however, mean that residents' status cannot be improved. Moreover, many initiatives are in early stages of development, and it is always possible that future evaluations may yield evidence of their effectiveness. At present, however, removing the protections of a regulatory system that has some degree of effectiveness, as demonstrated in the Report, in lieu of quality improvement initiatives of unproven effectiveness could risk the health and safety of the nation's vulnerable nursing home population. Even if supportive evidence emerges in the future, the question of how these interventions relate to the system of survey and certification remains.

Evaluation of HCFA's Nursing Home Survey and Certification System

Background

The Omnibus Budget Reconciliation Act of 1987 (OBRA '87) legislation and ensuing regulations and guidelines generated:

- New standards in the area of quality of care, resident rights, resident assessment, and quality of life;
- The Resident Assessment Instrument (RAI), including the Minimum Data Set (MDS), a standardized assessment instrument for all residents in nursing homes;
- A more outcome-oriented survey that emphasizes gathering information directly by observing and interviewing residents;
- Training standards and competency evaluation for nursing assistants; and
- New intermediate enforcement remedies that augmented the rather limited existing options for responding to facility noncompliance with program requirements.

On July 1, 1995 the new enforcement regulation, the final key provision of OBRA '87, was implemented. The intent of the new enforcement process was to provide solutions to several longstanding problems in Federal regulation: cyclical nursing home noncompliance with program requirements; the lack of options for addressing noncompliance; and the potentially lengthy intervals between the identification of a nursing home's compliance problem and its correction. Abandoning the hierarchical requirement systems, the regulation created a system capable of detecting and responding to noncompliance with any requirement. As described in its preamble in the *Federal Register*, the enforcement regulation was "built on the assumption that all

requirements must be met and enforced and that requirements take on greater or lesser significance as a function of the circumstances and resident outcomes in a particular facility at the time the survey.”

Perhaps the most fundamental question with respect to designing the required study about the effectiveness of the current survey is the criterion by which effectiveness is to be assessed; specifically, with what is the current survey to be compared? Two kinds of “effectiveness” comparisons seem both feasible and relevant. First, it is important to know the consequences of the major OBRA ‘87 reforms that were implemented in October 1990, compared to the enforcement system that preceded it. Second, it is important to know the consequences of the final set of OBRA reforms, particularly the enforcement provisions, implemented July 1, 1995, as compared to the enforcement system that preceded it.

With respect to the first comparison, the effectiveness of the initial OBRA reforms, a variety of studies were carefully reviewed for this report. With respect to the second comparison, the effectiveness of the final set of OBRA reforms, two sets of analyses were conducted: one assessed whether residents improved on a number of *outcome* measures due to the implementation of the July 1, 1995 enforcement provisions; the other empirically examined whether a number of survey and enforcement *processes* were in practice working as intended.

Effectiveness of OBRA ‘87 Provisions Implemented in 1990

In the report we have addressed a number of studies that focus on the effectiveness of aspects of the OBRA ‘87 provisions implemented in 1990.

Evaluation of the Resident Assessment Instrument (RAI)

A carefully designed evaluation of the nursing home RAI, a clinical assessment tool consisting of the MDS and a number of problem-focused Resident Assessment Protocols (RAPs), was conducted under contract to HCFA. The results of the RAI evaluation indicated that rates of hospitalization improved quite markedly. On other measures, selected health conditions, and function status measures, evaluators found both improvement and deterioration. However, improvement appeared to outweigh deterioration. Also, improvement occurred in arguably the more crucial areas addressed by the RAI.

Although the improvement appears real and due to the OBRA ‘87 reforms, commenters have found it less clear that the improvement was due to the RAI care planning component of OBRA ‘87, as argued by the investigators.

Study of Changes in the Use of Psychopharmacological Medications

This report presents an exhaustive review of the regulation of psychopharmacologic medication use in U.S. nursing homes from 1954 to 1997. In general, there was a consensus that antipsychotics were overused and antidepressants were under-used before OBRA ‘87. These

medications were specifically targeted in the OBRA '87 guidelines. A synthesis of several studies found improvement in the appropriate use of these medications, with the use of antipsychotics declining by 52.3 percent and antidepressants increasing by 97 percent (which equates to 24.9 percent antidepressant usage rate in 1997). This level of utilization of antidepressants is consistent with research on nursing home prevalence rates for major depressive disorders and depressive symptoms.

The magnitude and timing of the trend data in the use of psychopharmacologic medications combined with the results of separate studies designed to assess OBRA '87 impact indicate that the positive changes observed were due to OBRA '87. This is particularly true with respect to the utilization of antipsychotic and antidepressant medications drug categories that were specifically targeted in the OBRA '87 regulations and guidelines. This does not mean that other factors were unimportant. Indeed, it can be argued that some of these other factors, for example, the evolution of published knowledge and practices of geriatric medicine, contributed to the social and political process that led to the OBRA '87 statutes, regulations, and guidelines in the first place. These other factors, however, were not in and of themselves sufficient to change the general pattern of inappropriate use of psychopharmacologic medications in nursing homes. Only with the implementation of OBRA '87 was an abrupt change seen for the better. Hence, it appears that regulation was at least a necessary condition for the improvements observed. This conclusion is supported by a 1997 survey of randomly selected nursing home administrators in which 77 percent indicated that inappropriate psychopharmacologic medications had been reduced in their facilities in the last two years. Thirty-eight percent of these nursing home administrators said the reason these medications had been reduced was the OBRA '87 regulations.

Effectiveness of OBRA '87 Provisions Implemented in 1995

Stakeholder Perceptions of How the Current System is Working in Practice

Perceptions of the effectiveness of the current system were elicited from nursing home administrators, ombudsmen, consumer advocates, residents, family members, State surveyors, and nursing home personnel. Feedback was obtained in separate surveys of nursing home administrators and ombudsmen, as well as a series of listening sessions with providers, consumer advocates, ombudsmen, residents, family members, facility staff, and State surveyors. A survey of about 720 nursing home administrators using closed-ended yes/no or ranking questions had fairly positive responses related to changes made in response to the new survey and enforcement systems and administrators' satisfaction with the accuracy of the survey process. Results from the administrators' survey suggest that although they are generally satisfied with the accuracy of the certification survey process, they would prefer to have the option of deemed status. A second survey consisting of in-depth interviews with staff and management from 20 facilities, however, produced varied feedback with some negative responses about HCFA's survey and enforcement procedures. Many administrators commented that the "world view" of the survey process is based on a general distrust of providers, emphasizing punishment rather than a collaborative effort toward the joint goal of quality care.

The consumer advocates and ombudsmen expressed concerns with inadequate enforcement, the predictability of the survey, and inadequate staffing. The results of the listening sessions appear later in this report in an already highly concentrated form, as do the ombudsman survey and the provider survey. In a summary document of this nature, it would be impossible to fairly represent the many concerns and comments expressed by the various stakeholders; therefore, the reader is referred to Chapters 16 and 20.

Evidence on Outcomes

While stakeholders' perceptions are important, they are not a substitute for an empirical analysis of how the new system is working. The goal of this analysis was to measure the impact of the new enforcement regulation on nursing home resident outcomes. Because the enforcement regulation as implemented on July 1, 1995, introduced potential penalties for individual deficiencies, facilities may have responded to the new process by improving the overall quality of care. This enhanced quality of care in turn may have improved resident outcomes.

In this analysis, four resident outcomes were analyzed at both the State survey area office level and at the facility level: (1) percent residents physically restrained; (2) percent residents with pressure sores; (3) percent residents incontinent of bladder; and (4) percent residents incontinent of bowel. To control for confounding variables and to investigate whether resident status improvements could be linked to the enforcement regulation, a quasi-experimental study design was implemented that took advantage of the staggered timing of the new regulation.

The results of this analysis offer suggestive evidence that the new enforcement regulation was effective in improving resident status outcomes. At the area office level, the regulation is associated with a 9 to 10 percent reduction in bladder and bowel incontinence rates. There also is some evidence at the facility level that the new enforcement regulation had a very small, negative effect on the rate of physical restraint use. Consistently, facilities located in "low enforcer" area office jurisdictions who never or rarely cite facilities for substandard care were less responsive to the new enforcement regulation compared to facilities not located in "low enforcer" jurisdictions. It is not clear why the area office analysis indicated a positive impact of the July enforcement provisions on bladder and bowel incontinence rates, and the facility analysis indicated no effect in these areas. This could be due to reporting errors in the facility self-reported OSCAR data. These random errors tend to wash out when the variables used in the analysis are aggregated to the area office level. However, the reader should also bear in mind that the absence of a true control group raises the possibility, at least, that what appear to be enforcement effects are in fact due to other causes.

Evidence on Processes

The revised survey and enforcement system was implemented with a number of expectations about how it would work. As a matter of logic, it is possible that the new features of the survey and enforcement systems might work as intended, yet resident outcomes might not improve. We

have found the converse to be true: some of the new features may not in practice be working as intended, yet resident outcomes appear to have improved, as was discussed above.

Although it was not feasible to examine all the new processes generated by the July 1, 1995 changes to the system, we sought evidence with respect to the following selected processes related to: 1. administration; 2. problem identification; and 3. problem correction under the new system.

1. Administration

To what extent have changes in the survey and enforcement system affected administrative processes? One possibility was that administrative processes would clog under the new requirements. The enforcement regulation created new work for the State agencies responsible for conducting nursing home surveys. With respect to the question of whether the system can handle the increased workload, we found no evidence of any change in the frequency with which surveys are being conducted. Additionally, surveyors manage to conduct surveys at about the same rate as in the past.

With respect to the objective that the survey not only be unannounced but unanticipated, the current survey is much less successful. We found the survey interval to be quite variable. However, a facility has near certainty that it will never be surveyed on weekends or during evening hours. These data suggest that nursing homes could, for example, increase daytime staffing levels on Monday and Tuesday for a few months in anticipation of a survey, while not having to worry about weekend or nighttime staffing.

2. Problem Identification

One expectation of the new system was that even one instance of a violation of program requirements should result in a citation for deficient practice. All other factors being equal, this should, on average, have resulted in an increase in deficiencies. Contrary to this expectation, deficiencies declined, indicating that this new process of problem identification is not being implemented as intended. Although changes in facility quality could account for the decline in deficiencies, several pieces of indirect evidence suggest that improvements in facility quality are, at best, only perhaps a partial explanation of the observed decline. Further, it is important to be cautious in making any inferences about changes in surveyor behavior from changes in quality indicators. The indicators may only capture part of what surveyors are responsible for assessing.

Another concern with the new system is its capacity to identify serious problems. "Substandard quality of care" (SQC) was redefined to reflect instances in which the nursing home had more severe problems in providing quality of care or life. SQC is a very consequential designation under the new survey and enforcement systems. Facilities receiving a determination of SQC, in addition to any other remedies, lose their authority to conduct nurse aide training which, consequently, may make the hiring of nurse aides difficult. Because of these major consequences,

it is understandable that this designation might be contested by facilities, and surveyors and the State survey agencies might be hesitant to incur this conflict. Evidence suggests that States' ability or willingness to detect serious problems, as measured by the proportion of facilities that fall into the SQC category, varies considerably. Since the new enforcement provisions became effective, about five States have *no* facilities that are cited for *any* substandard care deficiencies; an additional four to 10 States cite almost none -- 1 to 2 percent of the facilities within their States. If a State has completed enough surveys, it would be expected that at least one (or a few) facilities should properly be designated with SQC. Hence, the extreme situation where no to very little SQC is reported most plausibly reflects surveyor (or State agency) behavior, not true quality differences. Under these circumstances, there is some question as to the capacity of the new system to identify serious problems, although serious problems may be identified as problems and classified on the enforcement grid as less serious.

Although the pattern of deficiency citations is consistent with the hypothesis that several States are not identifying problems as intended by the July 1, 1995 changes, this external analysis does not provide any direct evidence on the appropriateness of problem identification. In contrast, field studies conducted for HCFA by the Center for Health Services Research and Analysis (CHSRA), University of Wisconsin - Madison, provide more direct observational evidence that supports the more quantified analysis of citation patterns. CHSRA conducted two different types of studies, concurrent *surveys* and survey *observations*. For concurrent surveys, the CHSRA research survey teams completed standard Federal certification surveys simultaneous with recertification surveys being conducted by State survey teams. The survey observations were conducted by CHSRA observers who used an observation protocol. The surveys and observations were conducted on facilities broadly representative of nursing homes in the U.S. In general, the independent CHSRA researchers identified more serious problems as reflected in their scope and severity decisions; in no case did a State survey team report a higher scope and severity. These findings, consistent with the deficiency analysis reported above, indicate that the current survey, as implemented, does not sufficiently identify serious problems.

Since July 1995, there have been a number of media reports of abuse and neglect of residents in specific nursing homes in the U.S. It is difficult to know if the number of such reports has increased since July 1995, although this seems likely. It is of course possible that the new survey and enforcement provisions may have improved the outcomes for the average resident, as indicated in the research discussed above, and yet failed to protect a few residents from the kinds of egregious violations alleged in the media. Ultimately, it is difficult to evaluate the media allegations without an intensive, fact-gathering inquiry that is more characteristic of a court proceeding. Notwithstanding these cautions, we have made a limited effort to look behind some of these reports to see if something can be learned about limitations of the current survey system in addressing abuse and neglect.

Our assessment of these media reports and other evidence that has been marshaled to assess their credibility indicates, first, that malnutrition has been and continues to be a serious problem for

many nursing home residents. At present, the survey system does not appear to sufficiently address this problem. Second, the abuse of nursing home residents and the potential threat posed by hiring of nurse aides with violent, criminal histories may be a serious problem. It is likely that the current system under-identifies this problem.

3. Correction of Problems

Finally, there is the question of the effectiveness of the current system in correcting problems once they are identified. This question of problem correction is difficult to study retrospectively. It is also difficult to study without very expensive field work that would make direct observations at nursing homes over a fairly long period of time of what happens after specific problems are identified. We had neither the time nor the resources to conduct such an intensive investigation. We have, however, addressed this question by asking if the central mechanism of the survey process for correcting identified problems, Plans of Correction (POCs), resulted in real behavioral change on the part of providers or just paper compliance. Some assessment of this question was obtained from a modified ethnographic effort to collect and describe data collected from intensive interviews with representatives from a sample of 20 facilities who have had problems - often serious - cited under the new survey and enforcement systems.

We found evidence for both failure and success of the POC as an effective mechanism for problem correction. One example of failure was the frequently reported actions of facilities to provide in-service training to staff to correct identified problems. In the cases examined, there was no evidence bearing on the content and quality of the instruction, very high turnover of staff, and in one instance, a claim by a service union representative that workers were asked to sign an attendance sheet for an in-service they did not actually attend. On the more positive side is the example of a rural facility for which the survey team found substandard deficiencies. As a result of the required POC, the facility implemented a proactive means of resident behavioral monitoring, including meetings every two weeks of an interdisciplinary team to review any instances of individual resident behavior or resident interaction that warranted attention. The facility also implemented another team to review any reported falls and incidents involving residents on a weekly basis. While observing in the facility, the data collector witnessed this team in action during their weekly review. The incident review team is a self-directed effort that was still in place nine months after it was implemented. The other related improvement was that the admissions staff was more consistently completing accurate and comprehensive screening of any prospective residents.

Conclusions

A wide variety of evidence has been arrayed that bears on the three broad strategies for ensuring nursing home quality that Congress asked us to assess:

- With respect to granting deeming authority (the most likely organization to perform this function being JCAHO), evidence indicates that as presently structured, offering the deeming option to facilities would place many residents at serious risk. In contrast, the HCFA survey as typically implemented with its flaws, identifies many serious problems, allows less time for problems to remain uncorrected, and verifies compliance by an actual revisit as compared to JCAHO.
- An assessment of the second strategy, various regulatory incentives and non-regulatory nursing home quality improvement initiatives, provided little to no evidence that these efforts are effective and could supplant the normal survey process. At best, we would have to conclude that the evidence is not in.
- With respect to the third strategy, the existing system of survey and certification, evidence was produced that the OBRA '87 reforms implemented in October 1990 resulted in improved resident outcomes. Also, there is some suggestive but inconclusive evidence that the more recent enforcement provisions resulted in improvements in resident outcomes, although many of the enforcement processes we examined are not working as intended. There is a concern that several States never or very rarely cite a SQC deficiency.

The evidence examined in this study is supportive not only of regulation as the primary bulwark for quality assurance, but of enforcement needing to be more vigorously applied among the States. Although a thorough discussion of possible solutions to redress the problems in the Federal survey and certification process is beyond the scope of this report to Congress, the Department is currently in the process of identifying improvements to the current system.

National Citizens' Coalition for
NURSING HOME REFORM

Griff Hall, *Executive Director*
Scott Severns, *President*
Elma Holder, *Founder*

1424 16th Street, N.W., Suite 202
Washington, DC 20036-2211

Phone: 202-332-2275
FAX: 202-332-2949

July 21, 1997

William J. Clinton
President of the United States
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear President Clinton:

The National Citizens' Coalition for Nursing Home Reform (NCCNHR), a non-profit consumer organization that defines and achieves quality of care and life for nursing home residents, has serious concerns about proposed provisions in H.R. 2015 -- the House/Senate Conference Budget bill. While we support the government's efforts to reduce fraud and abuse in the health care system and to balance the budget, H.R. 2015 has the potential to seriously harm the quality of care and the quality of life of the nation's Medicare and Medicaid beneficiaries.

1) H.R. 2015 Allows States to Shift Cost-sharing onto Poor Medicaid Beneficiaries: The Senate bill allows states to impose new cost-sharing requirements on optional beneficiaries in their Medicaid programs. This provision would allow states to charge beneficiaries "limited" premiums, copayments, deductibles, and "any other charges." Beneficiaries whose income is below 150% of the poverty level could be charged up to 3% of their income. Beneficiaries whose income falls between 150% to 200% of the poverty level could be charged up to 5% of their income. Optional beneficiaries include many senior citizens and people with disabilities living in nursing homes. Under current law, these people are only allowed to keep \$30 of their monthly income as a personal needs allowance. These vulnerable people are already contributing virtually all of their income toward the cost of their health care, but now states could also require them to contribute a percentage of their \$30. This provision will also negatively impact the "medically needy," pregnant women receiving Medicaid, and other optional beneficiaries who receive a state supplement to their SSI. These beneficiaries, who are already spending most of their income on health care or who have little disposable income, will be required to share more of their health care costs under the Senate bill.

2) H.R. 2015 Caps Therapy Services Covered by Medicare Part B: H.R. 2015 includes a cap of \$1500 on therapy services provided to Medicare Part B beneficiaries. This cap will only allow beneficiaries about 30 visits to their physical and occupational therapists under current treatment rates. Many diseases and conditions require more than 30 therapy sessions. If beneficiaries are not allowed to receive the basic therapeutic care that their disease or condition requires, they are likely to become more dependent on the health care system and "medically needy." Thus, these beneficiaries are at a greater risk of needing nursing home care and more costly and advanced forms of medical interventions.

3) H.R. 2015 Harms Access to Health Care for Dually Eligible People: Currently, states are required to reimburse health care providers at Medicare rates for any services performed on a Medicare/Medicaid dually

eligible beneficiary. The Medicare rate is almost always higher than the Medicaid rate, thus giving providers more incentive to treat dually eligible people. People who receive both Medicare and Medicaid benefits have incomes less than 100% of the poverty level. They are the poorest and sickest of the country's citizens and generally have high health care costs. Compared with non-dually eligible Medicare beneficiaries, the Health Care Financing Administration found that the dual eligible are three times more likely to have incomes below \$10,000 and twelve times more likely to live in an institution. H.R. 2015 will allow states to pay providers of dual eligibles the Medicaid rate instead of the higher Medicare rate. This action will negatively impact access to health care for dual eligibles, the very people who need access to health care the most.

NCCNHR urges you to oppose the above provisions of H.R. 2015. Please feel free to contact our office at (202) 332-2275 to discuss the issue further. Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Griff Hall", written in a cursive style.

Griff Hall
Executive Director

cc. Christopher Jennings