"The Burden of Health Services Regulation"
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INTRODUCTION

Good morning. I am Vicki Gottlich, an attorney with the Center for Medicare Advocacy, Inc. I am presenting the testimony with my colleague, Toby Edelman, who could not attend today's hearing because she is speaking to nursing home ombudsmen in Florida. We thank you for the invitation to testify before the Subcommittee on behalf of Medicare beneficiaries and their advocates.

This hearing asks whether health care regulations add unnecessary and burdensome costs and whether these dollars could be redirected to providing health care insurance for uninsured people. From our perspective representing the rights and interests of older people and people with disabilities for more than 25 years, the answers are no. Regulations protect and promote the health and the quality of life of all individuals. When properly implemented and enforced, the rules save billions of dollars for the Medicare program. We use examples related to nursing home residents in our testimony because, by definition, nursing home residents are among the most vulnerable populations and the benefits to them from standards and regulations are well-documented.

OVERVIEW

Rules implementing federal Medicare legislation have helped to assure that Medicare beneficiaries have access to high quality health care. In the area of nursing homes, the Nursing Home Reform Law and federal rules have improved aspects of quality of care for residents. In addition, the good care practices mandated by the reform law and rules are cost-effective and save Medicare dollars.

However, while the Centers for Medicare & Medicaid Services can and does play an important role in protecting beneficiaries' access to high quality care, too often, the agency is timid and overly deferential to the health care industries it regulates. Beneficiaries can be harmed as a consequence. When the regulatory system is ineffective in preventing avoidable bad outcomes from occurring in nursing homes, the health care system pays more to treat the bad outcomes. When residents develop avoidable pressure sores and need to be hospitalized to receive treatment, the Medicare program pays for the hospitalization.

THE PURPOSE OF THE MEDICARE PROGRAM IS TO PROVIDE HEALTH CARE SERVICES TO BENEFICIARIES, NOT PAYMENTS TO HEALTH CARE PROVIDERS.

Congress enacted the Medicare program in order to provide health care benefits to older people and people with disabilities. Courts have repeatedly recognized and stated that the program is designed for beneficiaries, not providers. *Home Health Services, Inc. v. Currie*, 531 F. Supp. 476, 479 (D.S.C. 1982), *aff'd* 706 F.2d 497 (4th Cir. 1983) ("[T]he statute was obviously not enacted primarily for the benefit of the provider of services, but rather for the recipients of medical care benefits."); *Gartman v. Secretary of the United States Department of Health and Human Services*, 633 F. Supp. 671, 679 (E.D.N.Y. 1986)*; Mays v. Hospital Authority of Henry County*, 582 F. Supp. 425 (N.D. Ga. 1984).

THE ADMINISTRATIVE RULEMAKING PROCESS ENABLES BENEFICIARIES AS

WELL AS HEALTH CARE PROVIDERS TO PRESENT ISSUES AND CONCERNS TO THE CENTERS FOR MEDICARE & MEDICAID SERVICES.

Due to the complexity of health care programs and the expertise needed to administer them, Congress delegates responsibility to the Department of Health and Human Services to provide the details for its legislative enactments. The Centers for Medicare & Medicaid Services is the component within the Department that has expertise and is given the authority to implement the Medicare statute. CMS meets its duty to implement federal legislation, including Medicare, through a public rulemaking process.

While the rulemaking process is lengthy and time-consuming, it is also, at its best, both open and highly democratic. The rulemaking process allows all sectors of the public to express their views and to be heard. Beneficiaries and their advocates, as well as health care providers, participate in the rulemaking process in order to bring their experiences and concerns to the attention of CMS. Through their comments on rules, they explain the impact of rules on all segments of the public and offer suggestions to improve or strengthen rules to achieve their statutory goals. When CMS publishes final rules, it is required to respond to these public comments and to explain its rationale in making regulatory decisions. CMS is publicly accountable for its decisions.

MEDICARE BENEFICIARIES AND THEIR ADVOCATES SEE RULES AND THE RULEMAKING PROCESS AS HELPING TO ASSURE BENEFICIARIES' FULL ACCESS TO HIGH QUALITY HEALTH CARE.

While providers may see various aspects of the laws and rules as burdensome and excessive, beneficiaries often view these same laws and rules quite differently. Beneficiaries see the laws and rules as establishing a system that protects their rights and interests in receiving full access to high quality health care.

NURSING HOME CARE

The nursing Home Reform Law enacted by Congress in December 1987 and its implementation by the Health Care Financing Administration, the predecessor agency to CMS, are a clear example of how law and regulation work effectively both to establish a high level of care as the federal standard of care and to help improve the actual quality of care that residents receive.

The 1987 reform law was the most comprehensive revision to federal nursing home law since the Medicare and Medicaid programs were enacted in the 1960s. Congress based the detailed legislation on a series of hearings in 1987 in the three committees with legislative responsibility for the Medicare and Medicaid programs; on the 1986 report of the Institute of Medicine, *Improving the Quality of Care in Nursing Homes*, which itself was the result of several years of exhaustive research; and on recommendations of the Campaign for Quality Care, an *ad hoc* coalition of nursing home provider associations, health care professionals working in nursing homes, and residents' advocates, convened by the National Citizens' Coalition for Nursing Home Reform to identify areas of consensus about how best to translate the IoM's recommendations into federal law.

The nursing home reform law was based in large part on good practices that had been tried and proven effective in states. Requiring the training of nurse aides (who provide the majority of direct care to residents) and comprehensive assessment and care planning, guaranteeing residents' rights, and authorizing a broad range of intermediate sanctions that survey agencies could impose against facilities that failed to meet care standards were among the innovations of the legislation. These good practices involved both the care practices that nursing homes had developed and used with success as well as survey and enforcement practices that states had successfully used. The reform law made these good practices mandatory for all states and all facilities that chose to participate in the Medicare and Medicaid programs.

The Law and Implementing Regulations Promulgated by HCFA Have Promised Residents High Quality of Care and Have Led to Some Significant Improvements in Care.

The nursing home reform law and regulations and guidelines published by CMS' predecessor agency, the Health Care Financing Administration, to implement the law have led to demonstrable improvements in the care that residents receive. While the series of hearings held by Senators Charles Grassley and John Breaux in the Senate Special Committee on Aging, between July 1998 and September 2000, and by Senate Finance Committee in July 2003 documented that grave and unconscionable problems remain in the quality of care provided by too many nursing homes, the hearings demonstrated that these problems result primarily from the lack of strong public enforcement of the care standards, not from the statutory and regulatory standards themselves.[1]

The Reform Law Required Reduction in the Use of Physical and Chemical Restraints.

The requirement to reduce the use of physical and chemical restraints was based on good care practices in some nursing homes that had reduced or entirely eliminated restraints. At the time the law was enacted, however, a more common view in the nursing profession and the nursing home industry was that restraints would protect residents from injuries and falls. As a consequence, in the

[1] The Institute of Medicine's 2001 report *Improving the Quality of Long-Term Care* also identified "serious deficiencies" in assessment and enforcement of care standards as the cause of continuing serious care problems in nursing homes. Institute of Medicine, *Improving the Quality of Long-Term Care,* 251 (2001) [hereafter IoM, *Improving the Quality of Long-Term Care*].

late 1980s, an estimated 41% of all residents were physically restrained.[2]

[2] *Id.* 79.

The reform law adopted the best practice from the restraint-free movement (which recognized that restraints in fact caused more injuries to residents than restraint-free care), changed the paradigm of care on a national scale, and led to a reduction in restraint use for residents. The most recent national data indicate that in December 2003, 8.79% of residents nationwide were physically restrained.[3] Freeing residents from restraints was documented to be not only better from residents' perspective, but also a less costly way of providing care.

As Joani Latimer, a nursing home residents' advocate, wrote in the Journal of the American Society on Aging, "good law takes everyone to a higher standard."[4] The reform law set a new standard regarding restraints. When the New York-based Commonwealth Fund supported a project several years ago on restraint reduction in nursing homes, project staff asked facility staff why they participated in the research. Many answered that since the reform law now required reduction of restraints and facilities would be evaluated by the survey agency by this different standard of care, they were motivated to learn how to comply with the new rules most effectively. The project gave them that opportunity.

In a 2001 report, the Institute of Medicine attributed the reduction in the use of physical and chemical restraints nationwide, which it called "the greatest improvement in nursing home care,"[5] to

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[3] American Health Care Association, *Medical Condition, Mobility, CMS OXCAR Data Current Surveys, December 2003* http://www.ahca.org/research/oscar/rpt_MC_mobility_200312.pdf. These data are self-reported by facilities and unaudited by survey agencies.

[4] Joani Latimer, "The Essential Role of Regulation to Assure Quality in Long-Term Care," *Generations*, Vol. XXI, No. 4, 13 (Winter 1997-1998) [hereafter Latimer, "The Essential Role of Regulation"].

[5] IoM, *Improving the Quality of Long-Term Care*, *supra* note 1, 79.

the requirements of the reform law:

> [M]any facilities have successfully reduced the inappropriate use of physical and chemical restraints. The focus of increased regulatory scrutiny on these two areas of care was a major contributing factor in reductions in both of these.[6]

Reducing the use of restraints is good care; it is also a less expensive way to provide care to residents.[7]

The Reform Law Required Standardized Resident Assessments.

[6] *Id.* 77.

[7] Charles D. Phillips, Hawes, C., and Fries, B., "Reducing the Use of Physical Restraints in Nursing Homes: Will It Increase Costs?" *American Journal of Public Health, Vol.* 83, 342-348 (Mar. 1993).

Another beneficial aspect of the 1987 reform law was the requirement that all facilities assess residents using a comprehensive, standardized, reproducible assessment instrument. The assessment would identify "potentially treatable or reversible causes of functional impairment" and would be used to plan each resident's care in the individualized care-planning process.[8]

The new resident assessment instrument, known as the minimum data set, or MDS, was developed through an intensive public process that involved all sectors of long-term care and included extensive testing. Although the nursing home reform law explicitly permitted states to develop their own assessment instruments, all states chose to use the assessment instrument and process that were developed by HCFA.

An evaluation of the impact of the MDS in 1996 found that the new assessment process improved care outcomes for residents. The study found, among other changes:

- "a 24 percent increase in the accuracy and comprehensiveness of information in the residents' nursing home records."
- "a 17 percent increase in the number of problems that are addressed in residents' care plans."
- "a 30 percent increase in the use of hearing aids for persons with hearing difficulty."
- "a 27 percent increase in the use of behavior management programs for residents who wander, display physical aggression, or resist nursing care."
- "Residents with bowel incontinence were almost twice as likely to receive a toileting program."
- "a 29 percent decrease in the use of indwelling urinary catheters."
- "a 28 percent decrease in the proportion of residents with little or no activity."[9]

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[8] Charles D. Phillips, Hawes, C., Mor, V., Fries, B.E., and Morris, J.N., "Geriatric Assessment in Nursing Homes in the United States: Impact of a National Program," *Generations* (Journal of the American Society on Aging), Vol. XXI, No. 4, 15, 16 (Winter 1997-1998) [hereafter Phillips, "Geriatric Assessment"].

[9] Catherine Hawes, "Assuring Nursing Home Quality: The History and Impact of Federal Standards in OBRA 1987," 6-8 (Commonwealth Fund, Dec. 1996).

The increase in positive care outcomes and decline in negative care outcomes that resulted from implementation of the MDS had a price tag – they saved Medicare dollars. Providing good care to residents and more accurately identifying and meeting residents' care needs also led to reduced instances of hospitalization. Dr. Catherine Hawes reported that introduction of the MDS led to a 26% reduction in hospitalization of residents, resulting in an annual estimated savings to the Medicare program of two billion dollars in hospital costs in 1992 alone.[10]

While use of the MDS led to an increase in positive health outcomes for residents and, at the same time, significantly reduced costs to the Medicare program, administrators and nurses who were questioned about the MDS reported mixed feelings about the new assessment tool. Dr. Charles Phillips, et al., reported that 43% of clinical staff were "resistant" to using the MDS and that 68% of administrators complained about the "excessive paperwork burden."[11]

> However, a majority of both administrators and nursing directors agreed that the RAI had positive effects on quality: some 59 percent of nursing directors reported that the RAI improved the quality of residents' clinical assessments, 69 percent that their staff's assessment of residents' functional status improved, and 75 percent acknowledged that the RAI was more useful than the assessment system used in the past. Finally, 78 percent of nurses reported that the RAI improved their ability to detect clinically meaningful changes in resident functioning.[12]

Health care providers may find fault with regulations even when they recognize the improved health care for beneficiaries (and cost savings to the Medicare program) that result.

QUALITY OF HEALTH CARE

Rules and regulatory systems also require and promote high quality of care for beneficiaries. This purpose of the regulatory system is also of critical importance to beneficiaries.

Ms. Latimer reports that regulation is necessary in the health care area, particularly in long-term care, because market forces may be unable, alone, to assure high quality of care for beneficiaries.[13] The factors that may make the marketplace work as a mechanism assuring high quality of products are largely absent in health care. Health care consumers may be inadequately informed; may have little choice among health care providers (because of insurance limitations or provider discrimination against program beneficiaries); and may be required to make decisions at a hurried, stressful time. Moreover, the consequences of their decisions often cannot be reversed. People can

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[10] *Id.* 8.

[11] Phillips, "Geriatric Assessment," *supra* note 8, 16.

[12] *Id.* 16-17.

[13] Latimer, "The Essential Role of Regulation," *supra* note 4, 10.

choose to buy a different television set if the one they buy breaks. Similar opportunities are unlikely in health care. Health care that is denied or inadequately provided may not be able to be fixed or corrected.

The Institute of Medicine's 1986 report on nursing home quality rejected reliance solely on market forces to improve the quality of long-term care:

> [H]istorical experience hardly supports an optimistic judgment about the effects on quality of care of allowing market forces to exert the primary influence over nursing home behavior. Nursing homes were essentially unregulated in most states prior to the late 1960s. Their operations were governed almost entirely by market forces, and the quality of care was appalling.[14]

As noted above, the IoM's report was the blueprint for the nursing home reform law that Congress enacted in December 1987. Fifteen years later, the Institute of Medicine reiterated its support for a regulatory model to assure quality in long-term care.[15]

The value of a regulatory system to assure quality of care for nursing home residents was also firmly recognized by the California Supreme Court. In a 1997 decision, the Court recognized that regulatory systems are intended to prevent avoidable bad outcomes for residents: "the very purpose of the statutory scheme" is "preventing injury from occurring."[16]

Public support for regulation of nursing homes to address quality continues. The *New England Journal of Medicine* reported that a strong majority of Republican voters (57%) and Democratic voters (68%) in 2000 supported increasing regulation of nursing home quality.[17]

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[14] Committee on Nursing Home Regulation, Institute of Medicine, *Improving the Quality of Care in Nursing Homes* 5 (Mar. 1986).

[15] IoM, *Improving the Quality of Long-Term Care*, *supra* note 1, 141.

[16] *California Association of Health Facilities v. Department of Health Services,*16 Cal.4th 284, 940 P.2d 323, 336, 65 Cal. Rptr.2d 872, 885 (1997).

[17] "Health Policy 2001: The Implications of the 2000 Election," *The New England*

THE HIGH COST OF POOR CARE

In June 1991, the Senate Committee on Labor and Human Resources' Subcommittee on Aging reported, in a staff report,

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Journal of Medicine, Vol. 344, No. 9, 679, 681 (Mar. 1, 2001).

> Explosively expensive care is required to redress the effects of poor nursing care for residents in nursing homes. Inadequate numbers of nursing assistants, poorly supervised by licensed nurses, lead to breaks in care or inappropriate care. Basic care, food, fluids, cleanliness, sleep, mobility and toileting, when not carried out, lead to devastating outcomes for residents and additional expense for the government.[18]

The Committee report identified billions of dollars spent trying to correct poor health care outcomes that would have been avoided if good care had been provided to residents in the first place. Lack of toileting that led to incontinence cost $3.26 billion in 1986; poor hydration, nutrition, mobility, and cleanliness that led to pressure sores cost $1.2 to $12 billion; chemical restraints leading to falls and hip fractures that led to hospital care cost $2.6 billion in 1985; etc.

RULES ARE NEEDED TO MANDATE A SAFE ENVIRONMENT

Too often, facilities will not provide a safe environment for residents if the rules allow them to do otherwise. While sprinklers are recognized as the best mechanism to avoid deaths from fire, the rules "grandfather" in older facilities and allow them to use less effective measures, with predictable results. Last September, a fire broke out in a Tennessee nursing facility. Eight resident were killed in the fire, more died later, and 80 residents were sent to the hospital. After the fire, the corporate owner of the facility established a relief fund[19] and committed itself to installing sprinklers in all its

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[18] Subcommittee on Aging, Senate Committee on Labor and Human Resources, *Nursing Home Residents' Rights: Has the Administration Set a Land Mine for the Landmark OBRA 1987 Nursing Home Reform Law?* (Jun. 13, 1991).

[19] National HealthCare Corporation, "NHC's subsidiary facility damaged by fire" (Oct. 2, 2003), http://www.nhccare.com/press_releases/oct_2_2003.htm.

facilities.[20] The company estimated the cost of installing sprinklers in the 16 facilities that did not have sprinklers as $10,000,000[21] – approximately $625,000 per facility. The state began considering legislation to require sprinklers and the National Fire Protection Association is now calling for all nursing homes nationwide to be equipped with sprinklers.[22]

COMPLAINTS ABOUT REGULATORY BURDEN OFTEN MASK PROBLEMS WITH ACCESS TO OR QUALITY OF HEALTH CARE

[20] National HealthCare Corporation, "NHC to Retrofit Nursing Homes with Sprinklers" (Oct. 7, 2003), http://www.nhccare.com/press_releases/oct_7_2003.htm.

[21] National HealthCare Corporation, "NHC Estimates Cost of Sprinklers $10 million" (Oct. 8, 2003), http://www.nhccare.com/press_releases/oct_8_2003.htm.

[22] National Fire Protection Association, "NFPA president calls for fire sprinklers in all nursing homes; Recent tragedies show more must be done to keep elderly, disabled safe" (News Release, Oct. 16, 2003), http://www.nfpa.org/PressRoom/NewsReleases/NursingHomes/nursinghomes.asp.

A current problem experienced by home health agencies and enrollees in Medicare Advantage (formerly Medicare+Choice) health plans illustrates this point. In January of this year regulations went into effect to establish a "fast track" appeals process when a Medicare Advantage plan proposes to terminate home health, skilled nursing facility, or comprehensive outpatient rehabilitation facility (CORF) care.[23] The new procedure, established as part of the settlement of a law suit brought by the Center for Medicare Advocacy,[24] requires the provider to give the enrollee notice of the right to seek pre-termination review no later than two days before the proposed termination or, if the span of time between services exceeds two days, no later than the next to last visit.[25]

Home health agencies complain that the notice requirements are too burdensome, since Medicare Advantage plans only authorize one or two home health visits at a time. They say that the regulations would require them to provide notice of appeal rights at virtually every visit. The real issue is not that the notice obligations are too onerous, but that the Medicare Advantage plans are inappropriately denying their enrollees access to home health care to which they would have been entitled had they remained in traditional Medicare.[26] Further, it is the Medicare Advantage plans, and not the regulatory system, which creates the extra paperwork for the home health agencies by placing their own strict limitations on the amount of home care that is approved. The solution to this problem is not to eliminate the requirement to provide enrollees with notice of their appeal rights, but to require Medicare Advantage plans to provide their enrollees with the same benefits that are provided to individuals who remain in traditional Medicare.

But what happens to people who rely on Medicare if CMS decides to relieve home health agencies of their notice obligations, rather than to address the access to care problem? We at the Center for Medicare Advocacy know from our long experience of representing Medicare beneficiaries that

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[23] 68 Fed. Reg. 16651 (April 4, 2003), adding 42 C.F.R. §§ 422.624, 422.626.

[24] *Grijalval v. Shalala*, civ. 93-711 (D.C.Az. Settlement Approved December 2000.)

[25] 42 C.F.R. § 422.424(b)(1).

[26] In traditional Medicare home health services are provided for 60 day periods of time pursuant to a plan of care signed by the treating physician. 42 C.F.R. § 424.22. There is no limit on the number of care plans that may be approved.

people who do not get notice of appeal rights do not exercise those rights, and they often lose out on medically necessary health care to which they are entitled. We also know, first hand, that when our clients do not get the home health services to which they are entitled their condition deteriorates. They may be placed in a nursing home at a greater cost to Medicare, to Medicaid, and to their personal independence. And, unfortunately, we have seen such clients die.

AT TIMES, CMS HAS BEEN TOO TIMID IN EXERCISING ITS RULEMAKING AUTHORITY AND OVERLY DEFERENTIAL TO THE HEALTH CARE PROVIDERS IT REGULATES.

Although Medicare beneficiaries and their advocates recognize CMS' ability to implement federal legislation in ways that improve access and quality of care, we are concerned that the agency at times defers excessively to the health care providers it regulates.

In the nursing home area, CMS had difficulty implementing the strong enforcement approach of the nursing home reform law in the face of fierce and aggressive opposition by the nursing home industry. The weak enforcement system initially established by HCFA's guidelines tolerated high levels of facility non-compliance with federal standards of care, leading to the care crisis that Senator Grassley's and Senator Breaux's hearings vividly documented. Strong Congressional oversight and the Administration's Nursing Home Initiative announced in July 1998 redirected the agency's approach to enforcement, making it more consistent with the law and more likely to achieve its goals of assuring correction of deficiencies and sustained compliance by facilities.

The Center for Medicare Advocacy, Inc. is a private, non-profit organization founded in 1986, that provides education, analytical research, advocacy, and legal assistance to help older people and people with disabilities obtain necessary healthcare. The Center focuses on the needs of Medicare beneficiaries, people with chronic conditions, and those in need of long-term care. The Center provides training regarding Medicare and healthcare rights throughout the country and serves as legal counsel in litigation of importance to Medicare beneficiaries nationwide.