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HEALTH CARE:
Limited State Efforts to Assure Quality
of Care Outside Hospitals

Statement of
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Before the
Subcommittee on Regulation, Business
Opportunities, and Energy
Committee on Small Business
House of Representatives



Mr. Chairman and Members of the Committee:

I am pleased to be here today to discuss our report, Health Care: Limited State Efforts to Assure Quality of Care Outside Hospitals.¹ As you know, over the past two decades, efforts to control health care costs, rapidly developing technology, and increased competition have resulted in medical and diagnostic procedures that traditionally were done in hospitals increasingly being done in "freestanding" facilities, such as ambulatory care centers, ambulatory surgical centers, emergency centers, and general diagnostic centers. Relocating complex and risky medical procedures, such as surgeries and radiology services, to these freestanding facilities has prompted concerns about their ability to provide quality care. The concerns arise because of a perception among health industry observers that no one is taking steps to assure that consumers will receive quality care in these facilities.

Our review was made to determine the extent to which states are licensing, inspecting, and imposing sanctions against freestanding providers to protect consumers from receipt of poor quality care. Licensing assures that State laws and regulations are met and provides a framework for the delivery of quality care. It does not guarantee that quality health care will be delivered.

¹GAO/HRD-90-53, January 30, 1990.

It should be noted that federal quality assurance standards have been established for five types of freestanding providers-- ambulatory surgery centers, home health agencies, clinical laboratories, comprehensive rehabilitation centers, and hospices-- that choose to participate in the Medicare program. The Department of Health and Human Services (HHS) contracts with state health departments or other state agencies to do periodic inspections of these freestanding providers to determine compliance with Medicare requirements. Further, private-sector organizations, such as the Joint Commission on the Accreditation of Healthcare Organizations and the Accreditation Association for Ambulatory Health Care, conduct quality assurance surveys for some types of freestanding facilities that seek their accreditation.

SCOPE AND METHODOLOGY

We developed and mailed a questionnaire to health department licensing officials in the 50 states and the District of Columbia (51 states) to obtain information about state licensing, inspection, and enforcement for freestanding providers. We asked them to categorize their freestanding providers, using 16 broad definitions we gave them.

We reviewed state responses for consistency and completeness and, by telephone, attempted to obtain any missing data or resolve any inconsistency. We did not, however, verify the data provided

by the states. Our focus was on efforts states had taken on their own to regulate health care given by freestanding providers. Therefore, we did not ask about possible state efforts on behalf of the federal government to assure that providers comply with federal law and regulation under the Medicare and Medicaid programs.

With responses from each state and the District of Columbia, our results provide a comprehensive snapshot of the extent to which states were licensing, inspecting, and enforcing requirements for freestanding providers. They are based on the survey responses, which generally reflect state activity through September 30, 1987.

RESULTS IN BRIEF

States have been slow to license freestanding providers. In fact, as of September 30, 1987, they did not license or otherwise regulate most of the 16 types of freestanding providers covered in our survey. In preparation for this hearing, we called some states to see if there had been any change in their licensing requirements. While there has been some movement toward licensing, progress continues to be slow. We believe that the increased licensing activity reported in these phone calls has little impact on our overall results. Because of minimal state regulatory effort, we reported that consumers generally did not have adequate

assurance that unlicensed freestanding providers are offering quality care.

States with licensing requirements for freestanding providers, however, generally established minimum quality-assurance requirements. In addition, they conducted on-site inspections to determine compliance with the requirements. They have imposed few sanctions for deficiencies identified during inspections. State officials cited time-consuming appeals processes and the lack of intermediate sanctions, such as fines or restrictions on services that can be performed, as impediments to imposing sanctions. In addition, state officials expressed concern about the adequacy of their oversight and licensing efforts. Despite these concerns, however, state plans for expanding licensing requirements were typically limited to the one or two types of freestanding providers most frequently licensed by other states.

LIMITED STATE LICENSING OF FREESTANDING PROVIDERS

States frequently did not require freestanding providers to obtain a license to operate. Thirteen types of providers were generally allowed to operate in this manner. For example,

- no state required cancer treatment centers (either those providing treatment with radiation therapy or chemotherapy) or pain control centers to obtain a license, although they were known to be operating in 14 to 18 states.
- only 2 of 11 states with cardiac catheterization laboratories required a license.
- three of 34 states with diagnostic imaging centers required a license.
- four of 25 states with emergency centers required licensing.

States typically required only three types of providers to have a license to operate: alcohol and drug abuse treatment centers, ambulatory surgery centers, and home health agencies.

From the perspective of individual states, Montana and New York were the only ones that required each type of provider known to be operating in a state (five for Montana and eight for New York) to obtain a license. Four other states (Massachusetts, Nebraska, New Hampshire, and Rhode Island) required all but one of the types of providers known to be operating (from 6 to 10) to obtain a license. Usually, however, states were at the other end of the spectrum. For example, Iowa and Vermont did not require any of the types of providers operating (10 for Iowa and 6 for Vermont) to obtain a license. Ten other states required 25

percent or fewer of the types of providers known to be operating to obtain a license.

STATE QUALITY ASSURANCE

REQUIREMENTS

For those states that did require a particular type of provider to obtain a license to operate, the provider had to meet certain quality assurance requirements. The specifics of these requirements vary by type of provider and state but, of the 207 operational licensing programs, states reported requiring

- 73 percent to have quality assurance plans;
- 74 percent, credentialing processes for nonphysician staff;
- 67 percent, credentialing processes for physicians;
- 58 percent, systems for resolving complaints; and
- 48 percent, peer review programs.

INSPECTIONS GENERALLY

DONE ON SCHEDULE

With two exceptions, state licensing programs require on-site inspections, which states reported conducting for licensed freestanding providers at or near scheduled intervals, typically, at least annually. These on-site inspections generally include a

review of (1) patient records, (2) physician and nonphysician credentials, and (3) the provider's quality assurance program. States reported meeting or exceeding the required inspection frequency 75 to 100 percent of the time.

FEW SANCTIONS AGAINST
FREESTANDING PROVIDERS

Overall, states reported licensing more than 23,000 freestanding providers. Out of this number, for the 12-months ending September 30, 1987, 21 states reported imposing 165 sanctions (mostly fines and service restrictions) for deficiencies identified during inspections. The remaining states reported not sanctioning any freestanding providers. Lengthy appeals processes and the lack of available intermediate sanctions, such as monetary penalties and restrictions on the services that can be performed, were cited as impediments to imposing sanctions. States felt that these intermediate sanctions would be the most effective. More severe restrictions, such as license suspension or revocation (which were generally available to states that required licensing), were thought to be the least effective.

STATE CONCERNS ABOUT
ASSURING QUALITY OF CARE

Thirty-six state officials expressed concerns about assuring quality of care for freestanding providers. Typically, they saw a need for expanding regulatory oversight or providing additional resources to carry out quality assurance programs. They also questioned whether staff working for freestanding providers have proper credentials and training. Still others expressed concern about the public's false presumption that freestanding providers are regulated. Concerns officials raised included:

- Treatment and procedures performed by freestanding providers without state or federal oversight, such as laboratories in supermarkets, may not be safe (Colorado).
- Unless freestanding providers are regulated, the quality of care may not be as good as that provided in a hospital (District of Columbia).
- More staff are needed to provide oversight for existing providers as well as for future ones (South Dakota).
- Professional and nonprofessional staff of freestanding providers may not be adequately qualified and credentialed (District of Columbia, New Hampshire, Oklahoma, Texas).
- Staff lack training in infection control and emergency care in life-threatening situations (Louisiana).

Although most state officials expressed concern about the adequacy of their current quality assurance efforts, three expressed opposing views:

- Consumers expect too much of the government, which lacks funds to regulate all types of providers (Virginia).
- Studies are needed demonstrating the existence of quality-of-care problems before oversight is warranted (Iowa).
- Costs for regulating providers offering less than 24-hour care may not be justified (North Carolina).

STATES LACK SYSTEM TO
ADDRESS COMPLAINTS

Forty-two states reported receiving complaints about the quality of freestanding-provider care. Complaints included

- insufficient and unqualified staff and inappropriate care (Texas),
- alleged poor quality of care and lack of attention to patient needs (Illinois), and
- the staff's standards of medical practice (Illinois).

Almost half (23) of the states reported lacking a system for receiving and resolving complaints for licensed or unlicensed freestanding providers. A Texas official, for example, indicated

that although the state regularly receives complaints about care received from unlicensed providers, it was unable to provide specifics because the state does not keep records for unlicensed providers. A Colorado official recognized the need to build a case for regulation by documenting horror stories before going to the state legislature for authorization to license, but indicated that the state does not keep such records.

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In conclusion, freestanding providers offer consumers alternatives to care traditionally provided in hospitals and nursing homes. With the expansion of the number of these providers comes a challenge to ensure that they will give quality health care. One way to do this is through licensing. States that license freestanding providers generally establish minimum quality assurance requirements, conduct on-site inspections to determine compliance with requirements, and have the authority to impose sanctions against providers when necessary. This provides consumers with some assurance that licensed providers are capable of giving quality care. States, however, were slow to license freestanding providers. Further, they had limited plans to expand licensing requirements. Unless HHS or a reputable private accrediting organization is monitoring an unlicensed freestanding facility, consumers do not have adequate assurance that quality care can be provided.

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Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions you may have at this time.