MOBILE HEALTH SERVICES

OFFICE OF INSPECTOR GENERAL

OFFICE OF EVALUATION AND INSPECTIONS

JULY 1990

MOBILE HEALTH SERVICES

Richard P. Kusserow
INSPECTOR GENERAL

OEI-05-89-01331

JULY 1990

EXECUTIVE SUMMARY

PURPOSE

This inspection provides a national overview of the types and prevalence of mobile health services, the quality of these services, and the degree of regulation.

BACKGROUND

This is one in a series of reports on mobile health services. Two other reports describe: (1) the prevalence, conduct, and regulation of public cholesterol screening; and, (2) mobile health care providers that serve medically underserved and uninsured populations in public settings, or make physician housecalls.

We conducted these studies in response to a request by the Chairman of the House Subcommittee on Regulation and Business Opportunities. They provide information concerning mobile health services: services offered outside the traditional settings of a hospital, clinic, or physician's office. This report provides a preliminary look at the mobile health services industry. An in-depth study would require a great deal more research, given the wide variety of services and providers.

The services described in this study share one common characteristic: they bring healthcare to the people. Public screening reaches millions in community settings across the country. Providers using specially equipped vehicles go to employees on the job, visit the chronically ill in their homes, and park at migrant camps, homeless shelters, and rural crossroads. Large, high-tech equipment is loaded on trailers and shared by hospitals.

This study reveals that the mobile health services industry is changing and expanding. At present, public cholesterol screening is the only mobile health service which is both prevalent and nationally visible. While it is not clear whether or to what extent the industry is growing, some mobile health services appear promising in terms of providing health care in new and possibly cost-effective ways.

METHODOLOGY

We conducted an extensive literature review and held telephone discussions with 241 persons, including Federal and State regulators; persons from professional associations, State hospital associations and State consumer fraud agencies; experts; equipment and vehicle manufacturers; and providers of mobile health services. Most of the information is qualitative in nature and was gathered from a wide variety of sources. All had some knowledge of a particular service but none had a broad perspective on the industry as a whole. Few mobile health service providers register or are licensed as such, and no national or State database exists to track them. Hence, locating, much less systematically assessing, these services is difficult.

FINDINGS

Providers Deliver All Kinds Of Health Services In Mobile Settings. The Prevalence Of Mobile Health Services Is Difficult To Determine.

- Mobile health services are as diverse as public cholesterol screening, cardiac catheterization, and physician housecalls.

- Sponsors of mobile health services range from hospitals and health departments, to private entrepreneurs, to civic and professional groups.

Regulation Of Mobile Health Services Varies Widely For Some Services And Is Non-Existent For Others.

- Only Kentucky specifically regulates "mobile health services," as such.

- Most State and Federal regulation varies according to type of service, type of provider, place of service and/or cost of equipment.

Respondents Agree That Mobile Health Services Can Improve Access To Care. However, They Raise Questions Related To The Quality And Costs Of Such Services.

- There is concern that mobile testing may be compromised by inadequate quality assurance programs and ill-trained staff.

- There is no consensus on whether mobile health services are cost-effective.

- It is not clear whether mobile health services are any more prone to fraud and abuse than traditional health services.

RECOMMENDATIONS

The Public Health Service (PHS) Should Work With The States To Develop A Process For Identifying Emerging Mobile Health Services And Their Providers.

The PHS And The Health Care Financing Administration (HCFA) Should Develop Priorities And Protocols For Regulating Various Types Of Mobile Health Services.

AGENCY COMMENTS:

Both PHS and HCFA concur with our recommendations. The HCFA believes that PHS, with its technical expertise and resources should take the lead. The PHS agrees, but before developing priorities and protocols will review the available imperial research data and

governing legislative authorities to ensure protocols that contained defined measures of quality of care.

We wish to thank those in PHS and HCFA who commented on the report. The complete texts of their comments are contained in Appendix B. Several editorial changes were made based on PHS's comments.

TABLE OF CONTENTS

INTRODUCTION

PURPOSE

This inspection provides a national overview of the types and prevalence of mobile health services, the quality of these services, and the degree of regulation.

BACKGROUND

This is one in a series of reports on mobile health services. Two other reports describe: (1) the prevalence, conduct, and regulation of public cholesterol screening; and, (2) and mobile health care providers that serve medically underserved and uninsured populations in public settings, or make physician housecalls.

We conducted these studies in response to a request by the Chairman of the House Subcommittee on Regulation and Business Opportunities. They provide information concerning mobile health services: services offered outside the traditional settings of a hospital, clinic, or physician's office. This report provides a preliminary look at the mobile health services industry. An in-depth study would require a great deal more research, given the wide variety of services and providers.

While it is difficult to generalize about an industry that is so diverse, all of the activities described in this study share one common characteristic: they bring healthcare services to the people. Public screening, for example, reaches millions in community settings across the country. Providers using specially equipped vehicles go to employees on the job, visit frail, chronically ill elderly in their homes, and park at migrant camps, homeless shelters, and rural crossroads. Large, high-tech equipment, like that used for magnetic resonance imaging (MRI), is loaded on trailers and shared by hospitals.

Demand for mobile health services is driven by the interaction of public policies, social trends, the entrepreneurial spirit and technological advances. Federal health promotion policies have made the public aware of health issues and interested in taking an active role in their own health care, leading to interest in public screening. Public demands for ease and convenience at low cost have also fostered the growth of mobile services. Providers are seeking new ways to provide services in order to recoup revenue lost in part due to Federal cost containment efforts. Private entrepreneurs show increasing interest in providing health services traditionally offered by hospitals or clinics. Finally, mobile health services would not be possible without technological advances that have produced equipment adaptable to use in mobile settings.

This study reveals that the mobile health services industry is changing and expanding. At present, public cholesterol screening is the only mobile health service which is both prevalent and nationally visible. While it is not clear whether or to what extent the industry is growing,

some mobile health services appear promising in terms of providing health care in new and possibly cost-effective ways.

METHODOLOGY

We gathered information for this inspection through an extensive literature review and telephone discussions with 241 persons. By necessity, most of the information is qualitative in nature and was gathered from a wide variety of sources. All had some knowledge of a particular service, but none had a broad perspective on the industry as a whole. Few mobile health service providers register or are licensed as such, and States monitored only a very few providers such as x-ray facilities. Hence, locating, much less systematically assessing, these services is difficult.

The literature reviewed consisted of Federal and State laws, regulations and guidelines, research papers, studies, reports and newspaper articles. The people we talked with included:

- 119 regulators from all 50 States and the District of Columbia responsible for oversight of health care services;
- 25 Department of Health and Human Services officials, especially in the Public Health Service (PHS), including the Food and Drug Administration (FDA) and the Health Care Financing Administration (HCFA);
- 5 officials from the Occupational Safety and Health Administration (OSHA), Nuclear Regulatory Commission (NRC), Department of Transportation, and Environmental Protection Agency;
- 2 persons from the Office of Technology Assessment and the General Accounting Office;
- 37 persons from 17 professional associations, 10 State hospital associations and 5 State consumer fraud agencies;
- 14 experts with special perspectives on the issue;
- 5 equipment and vehicle manufacturers; and
- 34 providers of mobile health services.

We asked respondents to describe the mobile health services of which they were aware, and their prevalence. Even State regulators often relied on everything from first hand knowledge, advertisements and word of mouth, to State licensing or registration of providers or equipment to answer our questions. Some responses were only guesses or gut reactions. Even when

numbers were given, they reflected only those mobile services of which respondents were aware, not necessarily all those operating in the State in question.

FINDINGS

Providers Deliver All Kinds Of Health Services In Mobile Settings. The Prevalence Of Mobile Health Services Is Difficult To Determine.

- Health services as diverse as cholesterol screenings in shopping malls (by far the most prevalent type of mobile health service), cardiac catheterization and physician housecalls are being delivered in mobile settings.

Public Screening

Public Screening is the most nationally visible and prevalent type of mobile health service. By public screening we mean testing that is not requested by a doctor or is performed in a public setting. It is occurring in all 50 States and the District of Columbia. However, due to the "here today and gone tomorrow" nature of many public screenings, the number of screening providers operating in the nation is unknown.

Many screening providers set up in highly trafficked areas such as shopping malls, grocery stores, pharmacies, and even State Fairs. Such public screenings are often called "health" or "wellness fairs." In addition to actual screening tests, such fairs usually involve self-reporting from participants on their life style in order to develop a health risk appraisal.

Other providers also offer screening tests, usually as part of an array of health services targeted at a special population such as farm workers, runaways or employees. They set up at locations such as migrant camps, city street corners or industrial sites.

The public screening tests offered in mobile settings are very diverse, ranging from (1) blood tests to identify high blood cholesterol, diabetes, acquired immunodeficiency syndrome (AIDS), sickle cell anemia, pregnancy, or liver or kidney dysfunction; (2) x-rays, such as mammography to detect breast cancer; (3) pulmonary function tests to identify impaired lung function; and, (4) foot or dental examinations.

The most prevalent type of mobile screening service at this time is public cholesterol screening, which we describe in detail in another report entitled "Public Cholesterol Screening." Mobile mammography screening for breast cancer is also growing in prevalence. Four respondents reported that their States are, in the words of one, "flooded with mammography units." Some respondents believe that mobile mammography screening will continue to grow.

Diagnostic Services

We also learned of a few providers who conduct a broad array of screening and diagnostic testing out of specially-equipped trucks or vans. These so-called multiphasic providers are

for-profit entities, both private companies and hospital affiliates. The term "mobile" is particularly appropriate to them, since many have regional or even national service areas.

Multiphasic providers contract with entities such as unions, public and private organizations, or employers (such as heavy industry, State or Federal governments, professional sports teams, and even hospitals). They set up anywhere the client needs the service, whether a coal mine, industrial site or parking lot. Their clients often request such services in order to comply with OSHA standards, and providers tailor their services accordingly. A typical "menu" of services may include a patient history, height, weight, vision and hearing tests, blood pressure, blood tests, urinalysis, electrocardiogram, tonometry (for glaucoma), spirometry (for lung capacity), and a chest x-ray.

Mobile X-ray and Imaging

Mobile x-ray providers exist in almost all of the States. They most often screen the homebound or those in nursing homes for tuberculosis. However, some travel to industrial sites, such as a tire plant, or even gold or uranium mines, to screen employees for lung cancer or other diseases resulting from exposure to hazardous materials, like asbestos.

Mobile imaging services, specifically mammography and computerized axial tomography (CAT), which can detect tumors or bleeding in the brain or other body organs, exist in nearly half of the States. Ultrasound and MRI are other examples of such services. Providers station trucks, trailers or coaches housing this equipment outside the hospital or clinic requiring these diagnostic services for their patients.

Other Services

In a few States, more obscure yet innovative diagnostic procedures are also being performed in vehicles, although the potential risks associated with them limits the choice of setting to a hospital or clinic, where surgical and acute care backup is available. Twenty percent of the States report having a mobile lithotripter (which uses shock waves to shatter kidney stones) either operating or based in the State. The equipment is housed in the trailer of an 18-wheel truck and transported to hospitals or clinics. Cardiac catheterization, where a plastic tube is inserted into a blood vessel of the heart, is also being performed on a mobile basis. Only a few States knew of this type of mobile service. An article in *Part B News* (vol. 3, No. 10, 9/11/89) estimated that there are less than 100 freestanding cardiac catheterization labs. Some of these may be mobile. The article projects an expansion in freestanding labs because they are now allowed to bill HCFA directly rather than through a hospital, as in the past.

Housecalls may be making a comeback in America. Though few in number at this time, some providers have developed a "roadside manner" by using vans to bring not just the doctor, but the doctor's office, to a patient's home. Also, a few providers are using vans to take an array of health services to medically underserved and uninsured groups in public settings. Such services reach people who, for various reasons, have problems accessing care. Respondents see them as an alternative to no care at all, or to emergency room services. We describe both

of these innovative types of mobile services in a separate report entitled "Health Care on Wheels."

- Sponsors of mobile health services vary greatly, from hospitals and health departments, to private entrepreneurs, to civic and professional groups.

Health departments at all levels of Government, from Federal to local, provide mobile health services to their employees, the public at large, or targeted groups, as a public service.

Hospitals provide services in mobile settings, often as a public service or as a public relations or marketing strategy, to enhance their public image and increase their visibility. Seven out of 10 respondents from State hospital associations say that hospitals are offering public screening of some sort, to draw patients into the hospital for more profitable services. Hospitals may also contract out their services on a mobile basis to other entities, such as a nursing home, skilled nursing facility or even an employer or union.

Hospitals sometimes turn to mobile services as a cost containment measure, sharing equipment or contracting for a service with another entity, often a physician or physician group practice. They do this either because: (1) the hospital's utilization needs do not justify the expense of purchasing a highly expensive piece of equipment, like a lithotripter; or, (2) the State has certificate of need (CON) utilization requirements that one hospital is unable to meet, but that two or more hospitals can meet through sharing equipment. (See appendix A for a description of the CON process.)

Some respondents believe that as rural hospitals continue to close or limit services, remaining hospitals will increasingly turn to "putting their services in vans and sending them out to every town on every third Tuesday" in order to meet the routine health care needs of their communities. One respondent said that hospitals that fail to capitalize on this opportunity will lose this market niche to more enterprising providers.

Physicians and independent clinical laboratories are delivering mobile health services to make a profit. So are private entrepreneurs, both with or without a health care background. One respondent said that private entrepreneurs, showing an "amazing interest in health care," are increasingly providing health services traditionally offered by hospitals or physician clinics, such as screening, multiphasic testing or MRI. Another remarked, "If it's profitable, people will be out there doing it."

Unions and employers, either independently or under contract with other entities such as hospitals or private entrepreneurs, provide mobile health services to their members or employees. They do so as a company benefit or as a preventive health measure, to comply with OSHA requirements for mandatory testing for occupational exposure to environmental hazards.

Public and private agencies, community health centers and organizations such as the American Red Cross, the American Hospital Association, and even the American Medical Association may sponsor or deliver mobile health services, primarily as a public service.

Civic and professional groups are also sponsoring mobile health services, often as fundraisers. Insurance companies provide mobile services to assess the health of people seeking coverage.

Regulation Of Mobile Health Services Varies Widely For Some Services And Is Non-Existent For Others.

- Kentucky is the only State that specifically regulates "mobile health services," as such.

Kentucky regulates mobile health services through their CON process. Physician private practices and public service corporations are exempted. The State was experiencing an increasing variety of mobile health services and passed this law to help ensure State regulatory oversight over them. The regulation is very broad, providing minimum licensure requirements for entities providing such services as "mobile diagnostic imaging and examination services, mobile treatment services, and any other medical or dental services provided through the use of a mobile vehicle or performed at various locations."

- Most State and Federal regulation varies according to type of service, type of provider, place of service and/or cost of equipment.

For many mobile services, existing regulation addresses the general characteristics of the service, rather than its mobility. For example, Federal regulation covers x-ray services regardless of whether they are stationary or mobile. States vary in both the intent and extent of oversight of various medical services. They to regulate to: (1) comply with Federal mandates; (2) protect public health and safety; and, (3) contain costs. The extent of a State's regulatory oversight is frequently dependent on the funds and staff it has available, or on the level of legislative interest that can be generated in favor of regulation.

Mobile X-ray and Nuclear Medicine

Mobile x-ray is the most regulated type of mobile health service, and is regulated by the Federal Government and, in some form, by all but one State (Wyoming). On the Federal level, both equipment and providers are subject to some degree of oversight. The type and extent of State oversight vary widely.

On the Federal level, HCFA certifies portable x-ray providers seeking Medicare reimbursement. The FDA regulates the manufacture and installation of x-ray equipment, although there are no special provisions relative to mobile units per se. X-ray equipment manufactured after August 1, 1974 (pursuant to the Radiation Control for Health and Safety Act of 1968) is subject to FDA radiation safety performance standards. To ensure compliance,

FDA reviews documentation from the manufacturer and may also perform on-site inspections of the manufacturer's facility, test the product, or inspect equipment at a purchaser's place of business.

The FDA also requires that manufacturers and x-ray assemblers file a report each time they assemble an x-ray system, although there are no special provisions relative to mobile units. According to a staff person from FDA, the agency aims to review between 25 to 30 percent of all newly-assembled systems within a year of assembly, and usually contracts out this review function to a State.

State regulation of mobile x-ray runs the gamut - from minimal equipment safety standards to extensive equipment and operator safety standards, with mandated operator qualifications and quality assurance programs. The frequency of State on-site inspections of equipment ranges from annual, to every five years, to sporadic. One State respondent admitted that their on-site inspections consisted of only "very cursory checks" and that they were only "looking for gross problems." Eight State respondents admitted that some x-ray equipment in their States has never been inspected.

State-mandated quality assurance programs and operator qualifications for mobile x-ray services are neither prevalent nor universal. Staff range from certified radiological technicians (those who have passed the American Registry of Radiological Technicians exam or are certified by the State's to office assistants with no special training. One State respondent, echoing the concerns of several others, called the lack of quality assurance "a sore spot", and the issue of staff training "a thorn in my side . . . an MD gives a couple of lessons to someone off the street and they're qualified."

Mobile nuclear medicine services, which involve the use of radioactive byproduct material, are regulated by either the NRC or one of the 29 so-called "Agreement States", that is, States that have agreed to enforce, at a minimum, NRC regulations concerning such services. These States have the authority to license radioactive materials used or possessed within their borders. Oversight consists of health and safety surveys concerning the transportation, use, and disposal of radioactive by-product material.

Mobile Screening

Despite their prevalence, most mobile screening providers are unregulated. States more often than not consider screening tests to be a health assessment rather than the practice of medicine, since the purpose is to provide information on health status or identify risk factors rather than diagnose and treat a condition or illness.

Only some States have mammography screening guidelines for providers. Few States actually prohibit self-referral. One State, which does prohibit self-referral, also has a State law whereby "medical liability" is incurred by the screening radiologist if the patient does not have a primary care physician. The State respondent credited this law with minimizing

indiscriminate mammography screening in his State, such as that going on in neighboring States, saying that once a provider finds out about this law, "they don't want to get involved."

Major Medical Equipment

Major medical equipment used in mobile settings (i.e., lithotripters, MRI, CAT scanners and cardiac catheterization units) is most often regulated through States' CON process. This process requires that facilities such as hospitals justify utilization needs to the State in order to purchase major medical equipment whose acquisition costs exceed a State pre-determined dollar amount. (See appendix A for a further description of CON.)

There are gaps in regulation under CON, however. For example, regulation is sporadic because CON is slowly being phased out and exists in 38 States. Also, one major drawback of CON is that it does not apply to all mobile health care providers or services. For instance, one State regulates medical equipment costing $300,000 or more, while another has set the acquisition cost criteria at more than $500,000. Consequently, State monetary limitations exclude some major medical equipment from regulation. Also, as technology advances, the cost of medical equipment often correspondingly decreases.

Maryland has approached regulation of major medical equipment somewhat differently than other States. For example, since CON exempts some entities, such as physician's offices, from coverage, the State has attempted to make regulation universal. They have replaced CON with a licensure program applicable to all major medical equipment costing more than $600,000, whether owned by a hospital or another entity such as a private physician group or freestanding clinic. Maryland also attempts to regulate both the quality of use and the growth of major medical equipment regardless of setting.

While Maryland's program was initially conceived as part of a cost containment initiative, the State believes it has evolved into an effective quality assurance tool. Licensees are required to have a quality assurance program to ensure appropriate qualifications for all supervisors and operators of the equipment, and to provide for continuing education for all staff. They must also develop a system using objective criteria for both quality and appropriateness for the ongoing monitoring and evaluation of use of the equipment.

Mobile Laboratory Services

On the Federal level, mobile clinical laboratory services, regardless of site or volume of testing, are regulated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA of 1988). The HCFA will now review mobile clinical laboratories for certification. Prior to CLIA of 1988, these types of entities were not federally regulated. (Appendix A contains a description of CLIA of 1988.)

Twenty-four States would regulate any mobile clinical laboratory services through existing clinical laboratory regulations, although few State respondents were aware of the existence of such services. Regulation is varied, although mobile laboratories would qualify as a hospital,

physician or independent clinical laboratory and, therefore, have to meet the same requirements as their stationary counterparts.

Mobile Ultrasound

Mobile ultrasound equipment is regulated by only one State (Kentucky), even though other States have the statutory authority to regulate them. Some State respondents believe that ultrasound is not regulated either because States lack the money, staff or time to regulate, or because ultrasound has not been demonstrated to be potentially harmful to the patient.

Devices Used in Mobile Settings

- In the Federal arena, FDA approves medical devices for market, but there is no special review for devices used in mobile settings. States regulate the use of medical devices once they are approved for market.

The Medical Device Amendments of 1976 require that all medical devices be reviewed by FDA prior to marketing. However, there are no special provisions for the review of either portable devices or devices which can be used in mobile settings. Staff at FDA point out that, thanks to rapid technological advancement, many devices once used only in hospitals are increasingly being used in either the home or other non-traditional settings. (See appendix A for a description of the device review process.)

The use of medical devices, once they are approved for marketing, constitutes the practice of medicine and is regulated by States. The FDA imposes no special requirements on the use of equipment in mobile settings, although it has two special problem-reporting systems which are intended to target life-threatening problems related to the labeling or misuse of a device, no matter where used.

The Office of Inspector General is currently conducting internal control reviews of FDA's device review processes, as well as conducting an inspection on the subject of problem medical devices.

- The FDA also is responsible for protecting the public from unnecessary exposure to radiation from electronic products, some of which may be medical in nature.

The Radiation Control for Health and Safety Act of 1968 assigns responsibility to FDA for setting and enforcing radiation safety performance standards for electronic products, that is, all products or equipment capable of emitting ionizing or non-ionizing radiation, or sonic, infrasonic, or ultrasonic waves. Such products may be medical--such as diagnostic or cabinet x-ray systems, laser products or ultrasonic therapy equipment--or non-medical, such as microwave ovens.

The standards prescribe approaches to control radiation emissions. There are no standards specific to the use of the equipment in mobile settings.

Respondents Agree That Mobile Health Services Can Improve Access To Care. However, They Raise Questions Related To The Quality And Costs Of Such Services.

- According to respondents, the greatest benefit of mobile health services is that they provide access to health care.

Public screenings provide a convenient way for large numbers of people to undergo preliminary health risk assessments at a low cost. For many people, it can be a first step in seeking medical care.

Mobile health services can either serve to motivate people to see a doctor, or in some cases, actually be the doctor. Providers who bring services to the homebound, or to the medically underserved and uninsured in public settings, target these populations to bring them into the health care system. These types of services are described more fully in a separate report entitled "Health Care on Wheels."

Mobile health services may also help alleviate gaps in a community's health care system. They may replace services lost by closures of small rural hospitals or expand a small hospital's diagnostic testing capabilities, since they permit joint ownership or contracted services where there is insufficient capital or patient population to justify a permanent installation.

- Respondents are concerned that mobile testing may be compromised by inadequate quality assurance programs and ill-trained staff.

The major concern of respondents in this study has to do with the quality of testing conducted in mobile settings. Many States do not monitor mobile operations, raising questions in the minds of respondents about the safety and accuracy of mobile testing. Some State respondents suspect that mobile operations lack adequate supervision, that units do not have one qualified, accountable person in charge. And they express concern about whether quality assurance programs are in place at mobile testing sites. A separate report entitled "Public Cholesterol Screening" discusses these issues in depth as they relate to that type of mobile testing, which is both prevalent and highly visible across the country.

Respondents believe that quality is compromised most by the operators of the equipment, as opposed to the equipment itself. They stress that, in the words of one respondent, "the operator is the key" to quality testing. With the possible exception of hospital-owned or affiliated services, they feel that staff of mobile providers are often inadequately trained. They suspect that some for-profit providers train lay people on-the-job to conduct screenings, finding it too costly to hire highly qualified staff and still make a profit.

One State respondent noted further that, even with "cookbook type" tests, problems can still occur that require trained and experienced staff to detect and correct them. Respondents fear that operators who do not know how to properly use and maintain their mobile equipment may produce poor quality tests, or even unwittingly spread disease by ignoring proper hygienic conditions at test sites.

Some respondents advocate restricting those permitted to conduct mobile testing to only "health care professionals" who are trained to perform specific types of tests. Two respondents expressed the opinion that being a nurse, in and of itself, should not authorize a person to administer tests, since even a nurse may lack test-specific training.

- There is no consensus on whether mobile health services are cost-effective.

Relative to public screening, respondents say that while the public may pay less for a screening test in a public setting than in a hospital or physician's office, many fear that this is at the expense of quality. One State respondent said: "The price is certainly right for the patient." However, another countered: "You get what you pay for."

There were also questions about the effectiveness of public screening in targeting those in need of follow-up. Four State respondents questioned the value of screening which is not targeted to a population at risk. One of them posed the scenario of screening 20,000 people to find only 2 or 3 needing medical attention. They question the cost-effectiveness — to a State who conducts it, and to the public — of random screening that identifies such a small number of people at risk.

Multiphasic providers say that their services are cost-effective for both themselves and their clients because their operations are highly automated, efficient, and serve a high volume of patients, thus reducing the cost per patient. They say further that their services reduce the time lost from work by employees due to testing and prevent the development of major health problems by identifying them early on.

Hospitals may provide mobile health services at a profit or not. However, even if a mobile service operates at a loss, a hospital may continue to offer it in the hopes that it will encourage people to use their hospital.

Some respondents think that the sharing or contracting of expensive mobile health services, such as MRI or CAT scanners, is cost-effective for providers. However, one medical consultant reported that an MRI delivered in a tractor-trailer costs more than the $600 average price for a scan with a stationary MRI unit. Thus, even if these types of services are cost-effective for the provider in allowing the cost of the equipment to be shared, they may not necessarily be so for the patient.

In the case of cardiac catheterization, a change in Medicare reimbursement procedures may lead to cost savings. Freestanding laboratories, some of which may be mobile, can now bill

Medicare Part B directly rather than through a hospital outpatient department as in the past. As reported in *Part B News* (vol. 3, No. 10, 9/11/89), HCFA requires that a lab first get a determination from its carrier and peer review organization that the diagnostic services can be performed "appropriately and safely in the facility." The article noted that a HCFA official said that HCFA had become convinced that freestanding facilities could perform the procedure just as safely, and at less expense, than inpatient facilities. It noted further: "Rough estimates put the inpatient cost at about $6,000 and outpatient at $1,700-$2,600 for a left heart catheterization."

- It is not clear whether mobile health services are any more prone to fraud and abuse than traditional health services.

Respondents acknowledge that since mobile providers can set up for only a couple of hours or days in any one place, they may be "wide open for it (fraud)," yet they question whether mobile services are any more prone to fraud and abuse than other health services. Few respondents, including those from State consumer fraud agencies, were aware of specific cases.

In our discussions with Federal investigators, we did learn of a few cases where fraudulent providers have visited sites such as retirement homes, mobile home parks, or health clubs to conduct screening such as "ultrasound scan and body composition" tests, hearing or cholesterol tests, Doppler or echocardiogram imaging, "carotid artery" or other types of vascular testing. They have targeted elderly people and told them that Medicare will pay for the tests. The "patients" later learn that Medicare disallows all or part of the cost because the tests are considered screening rather than diagnostic testing.

Some of these cases have attracted press attention, particularly in Florida and California. One especially significant case resulted in a federal indictment and prison term, and the providers were permanently barred from Medicare. However, a six-agency task force continues to investigate these individuals because they continue to operate, although task force members say that they appear to have abandoned a mobile approach several years ago and no longer bill Medicare.

RECOMMENDATIONS

The PHS Should Work With The States To Develop A Process For Identifying Emerging Mobile Health Services And Their Providers.

The mobile health services industry is not well known or understood, even to State regulators with some responsibility for oversight. Yet this study reveals that health services of all types are increasingly being delivered in mobile settings, and that some of them may offer advantages related to access and cost.

We believe that the first step in learning more about mobile health services is to be able to identify services and their providers. As the Department's lead agency in matters related to health care services, we believe that PHS should assist the States in developing a process for this purpose.

The PHS And HCFA Should Develop Priorities And Protocols For Regulating Various Types Of Mobile Health Services.

Few of the services described in this report are regulated to any significant degree, whether by Federal or State Government. Yet, State respondents in this study raise serious concerns about the issue of quality relative to mobile health services. Furthermore, there are indications that some services are growing in prevalence, especially mobile testing of all kinds, which may already be reaching millions of Americans.

Accordingly, we recommend that PHS and HCFA prioritize specific types of mobile health services and develop regulatory protocols for them. Factors which should be addressed in developing these protocols include: (1) whether regulation is best carried out by State or local Government, or professional associations (for example, the Joint Commission for the Accreditation of Healthcare Organizations); (2) what role is appropriate for the Federal Government; (3) what special regulatory requirements are necessary given the mobile nature of these services; and, (4) what requirements are needed for the oversight of the equipment, provider, and operator for any given service.

For services involving laboratory testing, the development of protocols should be undertaken in conjunction with HCFA's implementation of the Clinical Laboratory Improvement Amendments of 1988.

Agency Comments:

Both PHS and HCFA concur with our recommendations and are willing to work cooperatively to achieve them. The complete texts of their comments are contained in Appendix B.

APPENDIX A

Current Regulatory Oversight Mechanisms for Mobile Health Services

The Clinical Laboratory Improvement Amendments of 1988 (CLIA of 1988)

These amendments brought all clinical laboratories under Federal regulation. Under CLIA of 1988, *all* clinical laboratories, regardless of site or test volume, must meet several requirements in order to obtain a certificate, or license to operate.

Prior to this, title 18 of the Social Security Act required that hospitals and independent laboratories meet certain conditions of coverage in order to receive reimbursement under Medicare and Medicaid. The CLIA regulated laboratories involved in interstate trade. With the passage of OBRA 1990, laboratories, including mobile laboratories, must now be certified under CLIA of 1988.

Each State has its own licensure requirements for clinical laboratories. Some are more stringent than those required by the Federal Government.

The FDA Device Approval Process

The Medical Device Amendments of 1976 require that all models of medical devices not on the market by the date of the amendments be reviewed by FDA prior to marketing in one of two processes: premarket notification (known as 510(k)) or premarket approval. Under 510(k), any device which FDA deems "substantially equivalent" to a device already on the market is not subject to any special testing by FDA. Only a few devices which are life-supporting or sustaining, or which represent a major change in technology, go through the much longer and more extensive pre-market approval process, where they are tested by FDA prior to approval.

The FDA Radiation Control Responsibility

The comprehensive Radiation Control for Health and Safety Act was enacted in 1968 to protect the public from unnecessary exposure to radiation from electronic products. Administration of the law is carried on through the setting and enforcement of performance standards to limit radiation emissions. The standards apply to products offered for sale or use in the United States, whether manufactured in this country or elsewhere.

Performance standards are prescribed for radiation-producing electronic products when FDA determines that Federal regulations are necessary for the protection of the public health and safety. The standards prescribe maximum allowable radiation levels and other approaches to control of radiation emissions without specifying design features.

State Certificate of Need (CON) Programs

The National Health Planning and Resources Development Act of 1974, Public Law 93-641, and its accompanying regulations, required States to implement CON program by July 1, 1978 or be subject to the loss of Federal funds for health planning as well as for other purposes.

The unnecessary construction or modification of health care facilities and duplication of health services were found to be substantial factors in the cost of health care. States developed CON programs to help control the rising cost of health care. They believed that CON would promote effective health planning by avoiding unnecessary duplication of health facilities and services, and would assist in providing quality health care at the lowest possible price.

State CON requirements vary widely, although all programs require that health care facilities justify to the State the need for purchasing major medical equipment or building new additions to, or modifying their facilities. The National Health Planning and Resources Development Act lapsed in 1987. As a result, CON is slowly being phased out and now exists in 38 States, which have continued to use it voluntarily, some of them for quality assurance purposes.

State and Local Regulations

Most health services are regulated in some way by State and/or local governments. This includes regulation of the certification and licensure of various medical professionals.

APPENDIX B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

MAY 14 1990

Memorandum

Gail R. Wilensky, Ph.D.
Administrator

ect: OIG Draft Report: Mobile Health Services, OEI-05-89-01331

The Inspector General
Office of the Secretary

We have reviewed the subject draft report. This report provides a national overview of the types and prevalence of mobile health services, the quality of these services, and the degree of regulation.

The report recommends that PHS and HCFA should develop priorities and protocols for regulating various types of mobile health services. We believe that PHS, with its technical expertise and resources, should have the lead in developing such priorities and protocols. We would then evaluate PHS' recommendations and apply them as appropriate. As an example of such a collaborative relationship, HCFA consulted with PHS in response to an inquiry about possible Medicare certification of mobile laboratories. We received PHS recommendations on the documentation needed to demonstrate the compliance of mobile laboratories with Federal requirements. We then incorporated these recommendations into the survey instructions that will implement the Clinical Laboratory Improvement Act of 1988. We believe this type of cooperative effort will achieve the goals that OIG is setting forth in its recommendation.

Thank you for the opportunity to comment on this draft report. Please advise us whether you agree with our position at your earliest convenience.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date MAY - 9 1990

From Assistant Secretary for Health

Subject OIG Draft Report, "Mobile Health Services," OEI-05-89-01331

To Inspector General, OS

Attached are the comments of the PHS on the subject draft report. We are supportive of improved mobile health care service delivery as part of a total system of health care. Our grant-supported State and community health center programs have effectively used mobile health services, particularly helping disenfranchised populations. However, we do have concern about the wide-range of medical practice situations covered in the report which do not differentiate between physician-referred and non-referred screenings.

We concur with the report's recommendations. However, before developing the full array of potential priorities and protocols, we will review the available empirical research data as well as the governing legislative authorities since the protocols will require well-researched and defined measures of quality of care.

James O. Mason

James O. Mason, M.D., Dr.P.H.

Attachment

COMMENTS OF THE PUBLIC HEALTH SERVICE ON THE OFFICE OF THE INSPECTOR GENERAL DRAFT REPORT "MOBILE HEALTH SERVICES" OEI-05-89-01331, MARCH 1990

General Comments

We are in agreement with the overall intent of this report for improved health care services through mobile health care delivery as part of a total system of health care. The State and community programs we have supported through grants for disenfranchised populations, such as the homeless, migrants, and those in rural areas, have used mobile services to meet the critical health care needs. However, it should be recognized that mobile health care service, such as screening programs, must be considered to be part of a total care system, that is, provided in collaboration with primary and tertiary care systems to ensure appropriate follow-up and referral for ongoing specialty care.

We have some concern about the wide range of health care services that are addressed in the report under the definitional grouping of "mobile health care services." We find that the report's groupings may be potentially confusing to the medical community, in particular, if the use of mobile health services for physician-referred, prescription service is construed to be the same as services for non-referred, mass-screening purposes. Such distinctions are important to physicians because of the degree of validity they place on the results. We suggest some refocusing of the findings and recommendations' section of the report to address the adequacy of health care by medical practice situation rather than merely grouping by means of delivery of the services.

We believe that benefits of mobile services should not be overlooked while focusing on perceived problem areas suggested by respondents to the study. For instance, the costs of mobile services may be justified if needy populations are served that would not be reached by fixed care providers on a regular basis. However, considerable judgment has to be employed in the use of mobile health services for screening programs for diseases such as AIDS because of concerns of patient confidentiality and adequacy of the testing procedures.

OIG Recommendation

The PHS should work with the States to develop a process for identifying emerging mobile health services and their providers.

PHS Comment

We concur. PHS' grant programs for community, migrant, and rural health centers provide support for mobile health services as a means of providing critical health care to medically underserved populations.

OIG Recommendation

The PHS and HCFA should develop priorities and protocols for regulating various types of mobile health services.

PHS Comment

We concur. However, before developing such protocols, PHS will review, in concert with HCFA, the available empirical research data as well as the governing legislative authorities. The protocols will require objective measures for evaluating the quality of the services provided in a way that is clinically meaningful. Our experience in evaluating mammography image quality has demonstrated to us that the development of such measures is a complex task.

Technical Comments

1. Page 1, Background

   We believe that OIG's characterization that the mobile health services industry is at an "embryonic stage" is inaccurate. Mobile x-ray screening has been around for decades, first with tuberculosis and now with mammography screening. We suggest that the industry be characterized as changing and expanding.

2. Page 2, Methodology

   The OIG statement that no "... State database exists to track ..." mobile health service providers is inaccurate. The statement should be modified to reflect that some areas of the mobile health service providers (for example, x-ray facilities) are monitored by the States.

3. Page 4, Screening Section

   A statement should be included that non-referred x-ray examinations are forbidden in most States. The exception to this rule is mammography screening. We have worked with the State health departments to eliminate non-referred, mass chest x-ray screening programs for tuberculosis. We are concerned that it would be a step backward if the OIG report could be interpreted in any way

as encouraging resumption of general, indiscriminate, non-referred mass x-ray screening programs.

4. Page 5, First Paragraph

We believe that the OIG should use "coal mines" instead of "gold mines" in view of the pneumoconiosis screening, and the much larger number of coal miners.

5. Page 6, Fifth Paragraph

We recommend that OIG insert the word "routine" before "health care needs" in order to differentiate the needs that are more serious from those that are less serious.

6. Page 7, Third Paragraph from the bottom

We recommend that OIG delete the phrase, "... often tend to ..." in the fourth sentence because it does not add any clarity to the sentence.

7. Page 7, Last Paragraph

We believe that OIG should change the phrase, "... FDA oversees x-ray equipment ..." to "... FDA regulates the manufacture and installation of x-ray equipment ..." to reflect a more accurate characterization of the Agency's role.

8. Page 8, First Paragraph

It would be more accurate to replace "... may contract ..." in the next to the last line with "... usually contracts ..."

9. Page 8, Third Paragraph

We believe that there are two problems with the words in parenthesis in the second sentence. First, it implies that you can be a qualified radiological technologist only by meeting one of the two criteria in the parenthesis and this is not true. The majority of the States do not have regulations to be met by machine operators and there are no doubt many well-qualified radiological technologists in those States who have not spent the time and money to take the voluntary American Registry of Radiological Technicians' examination. Second, the words, "State's equivalent" should be replaced by "are certified (or credentialed) by the State."

10. Page 10, Third Paragraph

The second sentence says, "there are no special provisions for the review of either portable medical devices or devices used in mobile settings." We believe this sentence conveys the erroneous implication that there is something wrong about not having special provisions. We believe the issue should be the quality of the service provided not whether the service is mobile. Applying the same high standards to both situations does not seem to be appropriate.

11. Page 10, Last Paragraph

We suggest deleting the words "... maximum allowable radiation levels and other." This general statement is inaccurate as written. The fluoroscopy standard does give maximum levels in the useful radiation beam but the other standards basically give only maximum allowable leakage rates. This is too complex to explain simply and a detailed explanation is not needed in this context.

12. Page 10, Last Paragraph

We believe the OIG should make it clear that the standards only apply to the manufacture and installation of equipment, not to its use.

13. Page 11, Second Bullet

We recommend that this bullet be changed to reflect that this concern applies to all mobile services not just mobile testing.

14. Page A1 - Under the FDA Device Approval Process

We believe the phrase, "... medical devices ..." in the first line should be replaced with "... models of medical devices not on the market by the date of the amendments ..." to improve the accuracy of the statement.

15. Page A1- Under the FDA Device Approval Process:

We believe that the Radiation Control for Health and Safety Act should also be mentioned in the Appendix. It has different and/or additional requirements for radiation emitting devices.