Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

PATIENT ADVANCE DIRECTIVES: EARLY IMPLEMENTATION EXPERIENCE

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EXECUTIVE SUMMARY

PURPOSE

To determine the extent of institutional compliance with the Omnibus Budget Reconciliation Act of 1990 advance directive provisions one year after enactment and determine the patients' understanding of their rights as well as the information provided to them under the law.

BACKGROUND

On November 5, 1990 the Congress enacted advance directive provisions as part of the OBRA-90. These provisions, however, became effective December 1, 1991. The intent of this law is to provide an opportunity for adult patients to express their desires about medical treatment in a variety of settings. An additional intent is to educate the entire population on advance directives such as living wills and the durable power of attorney for health care. This law creates no new rights for patients, it simply requires health care providers to inform individuals of any rights they have under State law, regarding patient self-determination.

It is important to evaluate early implementation efforts due to the law's potential effect on all Americans health care decisions. For this evaluation, a facility level review was undertaken at 72 facilities, in six States in a total of 12 counties. We interviewed staff responsible for implementing the requirements of the law at each facility, obtained required written materials and reviewed necessary documentation. Within these facilities, 1553 charts were reviewed and 348 patients or family members were contacted for phone interviews.

FINDINGS

MOST OF THE SAMPLE FACILITIES ARE COMPLYING WITH THE GENERAL LEGISLATIVE REQUIREMENTS.

THE LACK OF CLEAR AND CONSISTENT DOCUMENTATION IN PATIENTS' CHARTS INCREASES THE POSSIBILITY THAT THEIR TREATMENT WISHES MAY NOT BE FOLLOWED.

- *Many Sample Facilities had Missing Documentation Regarding Whether or Not the Patient had an Advance Directive.*
- *Performance In Clearly and Consistently Documenting The Existence of an Advance Directive In The Chart Needs Improvement.*
- *Only 60 Percent of the Patients With Advance Directives had Copies of the Directive in Their Medical Chart.*

TWENTY-ONE PERCENT OF THE PATIENTS IN HOSPITALS, NURSING FACILITIES AND HOME HEALTH AGENCIES HAVE ADVANCE DIRECTIVES.

TWO-THIRDS OF THE INDIVIDUALS INTERVIEWED HAD SOME UNDERSTANDING OF ADVANCE DIRECTIVES.

- *We Found No Evidence of Patients Being Pressured To Have Advance Directives.*
- *Only 32 Percent of the Facilities Provided Additional Information In Materials To Promote Patient Understanding of and Comfort With Advance Directives.*
- *Receiving Information on Advance Directives Appeared To Have Some Impact On Patient Interest in Obtaining A Directive.*

RECOMMENDATIONS

HCFA should develop and issue specific regulatory guidelines clarifying acceptable documentation methods to assist providers in meeting the requirements of the Federal Statute.

HCFA should encourage the Joint Commission for Accreditation of Health Organizations (JCAHO) to examine if the chart for each patient documents whether or not the patient has an advance directive, in addition to the existing JCAHO review item for advance directives.

HCFA, along with other appropriate Health and Human Service departmental offices, should provide leadership to develop a coordinated plan for educating the general public on advance directives.

AGENCY COMMENTS

We solicited and received comments from the Health Care Financing Administration (HCFA) on our draft report.

The HCFA did not concur with our recommendation regarding additional documentation guidelines in the regulations, believing that such changes would be overly prescriptive. However, because technical questions still remain for providers regarding compliance with the law we continue to believe that additional guidance would be helpful to providers. This guidance need not be overly prescriptive.

The HCFA generally concurred with our recommendation concerning the JCAHO review of medical record documentation but suggested that JCAHO's current process, which determines if a copy of the advance directive is present in a sample of records, addresses our concerns. As a result of this comment, we refined our second recommendation to

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INTRODUCTION

PURPOSE

To determine the extent of institutional compliance with the Omnibus Budget Reconciliation Act of 1990 advance directive provisions one year after enactment and determine the patients' understanding of their rights as well as the information provided to them under the law.

BACKGROUND

On November 5, 1990 the Congress enacted advance directives provisions as part of OBRA 1990[1]. The intent of this portion of the law is to provide an opportunity for adult patients to express their desires about medical treatment in a variety of settings[2]. An additional intent is to educate the entire population on advance directives[3] such as living wills and the durable power of attorney for health care. These provisions do not create any new rights for patients. The provisions simply require health care providers to inform individuals of any rights they now have under State law, regarding patient self-determination.

Senators Danforth and Moynihan introduced the provisions as the Patient Self Determination Act in October of 1989, to afford individuals the opportunity to participate in medical decisions affecting the condition and length of their lives[4]. Such an Act was needed to offset an imbalance in the relationship between health care consumers and providers[5]. Senator Danforth perceived that the caring component was being left out of medicine and patient rights were being trampled upon[6].

Because of the potential impact of these provisions on all Americans, it was important to determine if the spirit and letter of this law were being met. A facility level review of the requirements was necessary to determine if the provisions were being implemented appropriately. It was also crucial to determine if patients were being educated and allowed to participate in the health care decision process, or if additional paperwork had simply been added to the administrative process.

The Provisions

The advance directive provisions are contained in the Omnibus Budget Reconciliation Act of 1990. This section of the law became effective December 1, 1991, approximately one year after enactment, in all fifty States. During the interim year, health care providers participating in the Medicaid/Medicare programs were to develop both written policies and procedures and patient materials addressing directives under State law. Participating health care providers covered by these provisions include, but are not limited to,

hospitals, nursing homes and home health care agencies. The materials developed are to be provided to all adults upon admission to a facility or in advance of beginning care. Policies and procedures, as well as materials provided, must ensure compliance with State legislation and/or court opinions addressing patient directives. A description of State law must be included in information provided to all adult patients. Finally, the patient's record must state whether he/she reports having executed an advance directive[7].

While the advance directive provisions require health care providers to make this information available to all adult patients, certain activities are not required. The provisions do not require patients to complete any form of advance directive. In fact, the provisions expressly forbid requiring an advance directive as a requisite for treatment. In addition, the provisions do not override any State law allowing a provider to object to the implementation of an advance directive on the basis of conscience. However, in such a case policies on this topic should be included in the information provided upon admission.

Evolution of the Advance Directive Provisions

The advance directive provisions evolved both from case law and medico/legal considerations. The final legal decision drawing attention to the need to consider patient's wishes in health care decision making was provided in the Supreme Court ruling in the Cruzan case[8]. This case recognized a patient's right to accept or refuse treatment and endorsed the withdrawal of life support and the withholding of medical treatment when a patient's wishes were known[9,10]. This ruling helped focus the need to inform patients of their rights to state treatment preferences regarding life and death matters before undergoing medical treatment.

The evolution of medico/legal considerations over the past fifteen years also encouraged greater patient involvement in their medical care. These considerations took three forms:

1. Do not resuscitate order (DNR), a written order documented in the patient's medical chart to allow patients or family members to choose to forego further medical intervention in case of an event such as a cardiac arrest.
2. Living will, a document containing written instructions pertaining to an individual's treatment.
3. Durable power of attorney for health care, empowers an individual to appoint an agent or surrogate to decide for them should they become incompetent or unconscious.

Due to the patient's lack of knowledge about these devices, communication between the patient and physician had not increased. In addition, despite the frequent use of DNR orders, they often were not discussed with the patient or even the family. Studies found patients were only asked their preference for life prolonging treatment between 14 and 22 percent of the time[11,12,13], while family members were asked 33 to 86 percent of the time[14,15,16]. Further studies indicated the agreement between a potential proxy and the patient on preferences for life sustaining treatments ranged between 53 and 90 percent

for a family member[17,18], and between 38 and 89 percent for the patient's physician[19,20]. Thus, the literature indicates the wishes of the patient were frequently not considered before placing an order to forgo resuscitation. This reinforced the need for the advance directive provisions, which include patient education about advance directives as an important component.

Public and Institutional Response to Advance Directives.

Research on patients' interests in advanced care directives supports the need for the advance directive provisions. Studies have found between 89 and 93[21] percent of individuals surveyed desire at least one form of advance directive. However, two surveys indicate only 14[22] to 18[23] percent of individuals have either discussed their desires with their physicians or put them in writing.

In the realm of hospital policies on advance directives, a 1988 study of randomly selected hospitals noted that 67 percent of the respondents reported having a formal policy regarding advance directives[24]. However, of these hospitals, only 63[25] percent reported a policy requiring the patient to notify the physician if they had an advance directive. Only four percent of the hospitals had a policy of asking all patients whether they had ever completed an advance directive[26].

Concerns Regarding the Use of Advance Directives.

One concern addressed in the literature is the possibility that the advance directive provisions will have little impact. A study of New York State's legislation requiring a patient discussion before issuing DNR orders found no significant change in the number of decisions being made by patients. Both before and after the legislation, 80% of cases involving DNR orders were based on decisions made by family members[27].

Another concern relating to the impact of the advance directive provisions is whether patients will fully understand the information contained in materials provided, as well as the importance of the information. Studies show many existing consent forms require reading skills at the advanced college level[28] and even well-educated individuals often find it difficult to understand terms explained in health care plans to which they subscribe[29]. Concern also exists that patients may view the information as just another form and choose not to read it[30]. Another risk is that patients may be incorrectly informed of their rights due to discrepancies between State statutes and legal findings[31]. Additional concerns surround the issue of patients making involuntary or unreasoned decisions due to the initiation of the informational process upon admission, frequently a time of turmoil[32]. Finally, concern is expressed that facilities will encourage disadvantaged patients to sign a directive for financial reasons, to limit costs of potential extended treatment[33,34].

These concerns demonstrate a need to determine both the administrative compliance level, as well as compliance related to the level of patient understanding of advance directives. Researchers believe relying solely on a simple patient chart audit to determine compliance with the requirements of the provisions could be misleading. Such reviews do not measure patients' understanding of their rights or the lack of a requirement to have a directive to obtain medical treatment[35,36].

METHODOLOGY

This inspection reviewed both institutional compliance with the requirements of the advance directive provisions, and patient understanding of the information presented to him/her at time of admission or commencement of services. Institutional compliance was divided into two components, administrative compliance and chart documentation. Since the advance directive provisions were Federal in nature and applied to all Medicaid/Medicare facilities, all States and all hospitals, nursing facilities and home health agencies were initially included in our sample. Individuals who received care within each of these settings were also interviewed to ascertain their understanding of the advance care directive information they received.

While the content of State laws was not reviewed in depth[37], consideration was given to the type of advance directives allowed in the sample States[38]. Legislation in States generally allowed for the following advance directive possibilities:

1. Living Wills only (9 States)
2. Durable Power of Attorney for Health Care only (6 States)
3. Living Will and Durable Power of Attorney for Health Care (33 States)

A four stage, stratified random sample was utilized in this study. The initial stratification was based on the type of advance directive(s) legislation present in the State. Two States were randomly selected from each group. The six sample States were, Arizona, Florida, Maryland, Massachusetts, Michigan and Washington. After sample States were selected, two counties/county units were randomly selected from each State with probability proportionate to size. Size was defined as the total number of Medicare/Medicaid participating hospitals, nursing facilities and home health agencies in the county unit. County unit was defined as two or more contiguous counties in which one or more has fewer than the required number (two), of at least one type of organization included in the sample. Within these county units, two of each type of provider were randomly selected and included in the sample. Within each facility, 25 charts were randomly selected for review from all the admissions for the period, March 1 to April 30, 1992. For the facilities with fewer than 25 admissions, all admissions during the sixty day period were reviewed. Finally, five charts of living patients were randomly selected and contacted for personal conversations regarding their understanding of the information they received on advance directives. If five or fewer patients were admitted during the time period, all living patients were contacted and interviewed. Data were collected between May 11 and June 4, 1992.

	Number of Counties Visited	Number of Facilities Reviewed	Number of Charts Reviewed	Number of Patient/Individuals Interviewed
Hospital	12	24	591	120
Nursing Facility	12	24	424	113
Home Health Agency	12	24	538	115
TOTAL	12	72	1553	348

The data collected pertained to the presence or absence of specific materials and policies within the organization, the documentation of specific interactions and educational activities in the patient chart and elsewhere, and the patient understanding of information provided based on phone conversations with patients and other relevant individuals. In an effort to understand facility/agency outcomes, information was also obtained regarding difficulties facilities encountered in implementing the requirements of the advance directive provisions.

Information reported for the facilities and patient understanding are based on the sample data. Information presented on data from the charts is weighted and projected to the universe of all Medicaid/Medicare participating hospitals, nursing facilities and home health agencies. This projection represents 6.8 million charts. While some of the projections have poor precision due to the limited number of facilities and the four stage sampling technique, it is still felt that they represent a reasonable estimate of initial implementation efforts. Appendix B presents the unweighted and weighted sample data for the data presented on patient charts. Regression analysis was also undertaken on the sample data, with a cursory discussion included in the report and a more complete discussion of the regression results in Appendix A.

We conducted our review according to the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

MOST OF THE SAMPLE FACILITIES ARE COMPLYING WITH THE GENERAL LEGISLATIVE REQUIREMENTS.

Measures of Compliance With the Advance Directive Provisions Used to Form The Legislative Requirements Index*.

72	•	The facility has developed written policies and procedures explaining advance directives and the hospital's requirements pertaining to them.
69	•	The facility has developed written materials regarding advance directives and provides them to each adult patient upon admission or commencing services (both must be answered yes to obtain credit for this item.)
56	•	Materials provided to the patient clearly state that a patient does not require an advance directive to receive treatment.
69	•	Materials provided to the patient include a written explanation of the law pertaining to advance directives in that State.
67	•	The facility has provided staff education on the advance directive provisions, and has some form of documentation indicating education has been provided (both must be answered yes to obtain credit for this item.)
49	•	The facility has planned or provided community education on advance directives.

* numbers presented in italics represent number of facilities meeting this requirement out of a total of 72

Figure 1

Eighty-seven percent of the facilities demonstrate compliance in five or more of the index areas, and all facilities demonstrated compliance in at least four of the index areas. Forty-three percent of the facilities demonstrated 100 percent compliance in the legislative requirements index. When examining facility type, it is noted that hospitals have the highest mean index, 5.5, nursing facilities have a mean index of 5.3 and home health agencies scored the lowest, with 5.0 on the six point index. This demonstrates very little overall difference between facility types in complying with the general legislative requirements. The index total was derived by assigning one point to each of the six legislative requirements listed in figure one.[39,40]

The Legislative Requirement Most Frequently Unmet Was The Facility Responsibility To Provide Community Education.

Twenty-three of the 72 facilities in the sample, or 32 percent, had not planned or provided community education on the advance directive provisions. Home health agencies were the type of facility which most frequently had not provided community education. Twelve home health agencies, or half of the home health sample, had not provided this service.

While many facilities had not provided community education, half of the seventy-two facility contacts stated more information needs to be given to the public. Such public information would increase awareness of advance directives before individuals became ill and improve understanding of the terms when directives were explained. Generally, contacts at the facilities called for public service announcements on this topic and said government agencies, such as HCFA and Social Security, should include information regarding the topic with current mailings.

THE LACK OF CLEAR AND CONSISTENT DOCUMENTATION IN PATIENT CHARTS INCREASES THE POSSIBILITY THEIR TREATMENT WISHES MAY NOT BE FOLLOWED

Many Sample Facilities Had Missing Documentation Regarding Whether Or Not The Patient Had An Advance Directive.

Only 19 facilities, or 26 percent of the sample, had clear documentation stating whether the patient did or did not have an advance directive in 100 percent of the medical records reviewed. By contrast, in 15 percent of facilities less than half of the charts were clearly documented, including one of four nursing homes and one of five home health agencies.

PERCENTAGE OF CHARTS WITH DOCUMENTATION PRESENT: BY FACILITY

	Below 50 percent		50-75 percent		75-99 Percent		100 Percent	
	# of Facilities	% of Total	# of Facilities	% of Total	# of Facilities	% of Total	# of Facilities	% Row Total
All Facilities	11	15.3	11	15.3	31	43.0	19	26.4
Hospitals	0	0	5	20.8	14	58.3	5	20.8
Nursing Facilities	6	25.0	3	12.5	7	29.2	8	33.3
Home Health Agencies	5	20.8	3	12.5	10	41.6	6	25.0

While three facilities had no documentation in the medical chart as to whether a patient had an advance directive, two of these facilities did have documentation in the patient's financial folder, located in the business office. Additionally, some facilities would clearly document that patients had received information regarding advance directives, but would not consistently document whether or not the individual had a directive.

A statistical examination of the percent of charts with documentation present provided only limited insight (explaining 13.5 percent of the variation among facilities) into which factors affect the presence of clear chart documentation in each facility. The three factors having an impact on explaining the percentages of charts with documentation in each facility were:

- The lack of staff education or documentation of staff education on the topic
- The provision of staff education after the provisions were implemented
- Status as a for-profit organization

Facilities providing staff education on the topic after, rather than before, implementation of the advance directive provisions had a lower percentage of charts with documentation present. This supports the effectiveness of employee education and its impact on improving employee awareness and attention to this new procedure, supporting the need for the education requirement. The effect of the for-profit variable was positive, when compared to not-for-profit facilities, indicating a higher frequency of documentation in for-profit agencies. This finding could indicate for-profit organizations may be members of a chain and thus more likely to have received company-wide policies and materials that could be easily disseminated.

After accounting for the States included in the sample, two additional variables, location in Florida and whether the facility was a nursing home, had a significant negative impact on the percent of charts with documentation present. By controlling for the individual States in the regression analysis, the variables examined explained 23.8 percent of the variation in documentation between the facilities. There was no significant effect of whether the facility was a hospital, or home health agency, location in one of the other sample States, or from having a higher score on the legislative index in either analysis. For a further discussion of the statistical findings, see Appendix A.

In Sample Facilities, Information On Advance Directives Was Often Difficult To Locate Due To A Lack of Standardized Methods of Documenting.

Standardized methods of presenting chart documentation, within a facility, regarding advance directives may be an important issue in assuring the ability to locate information stating whether or not the patient has a directive. In an emergency situation, the ability to quickly locate this information would be important, as it could lead to different treatment approaches. When examining documentation methods it was noted that sample facilities documented in a variety of ways. When documenting in the chart, facilities generally used a standard form (either computer generated or photocopied), a written note in the

chart (generally in the social service section or nurses notes), or a standardized admissions assessment form utilized by the State in nursing facilities. Difficulties sometimes arose in locating the documentation since methods were not always consistent within the facility. In addition, several facilities may have kept documentation on a standardized form in the business office exclusively, or in the business office with a note appearing in the patient's chart. Many facilities had utilized various methods of documentation and had moved toward a more standardized facility format during the early months of the implementation.

Performance In Clearly And Consistently Documenting In The Chart Needs Improvement.

STATUS OF DOCUMENTATION IN PATIENT'S MEDICAL RECORD					
Facility Type	Documentation in Chart	No Chart Documentation	Documentation Elsewhere	"Unknown" Noted	"Comprehension Poor" Noted
All Types	80.5%	14.0%	1.7%	3.3%	.2%
Hospitals	86.2%	9.4%	0	4.4%	0
Nursing Facilities	46.0%	25.5%	26.7%	0	1.8%
Home Health	68.0%	31.5%	0	.03%	.5%

While the majority of charts had clear documentation stating "yes" the patient has an advance directive or "no" the patient does not have an advance directive, many charts lacked any documentation or contained ambiguous statements. In addition, some charts contained uncompleted directive forms, or only documentation that information on advance directives had been provided to the patient.

When examining provider types and their documentation efforts, some differences become apparent. Almost one-third of the charts in home health agencies and one-fourth in nursing facilities had no clear documentation indicating whether the patient did or did not have a directive. Additionally, about one-fourth of the charts in nursing facilities had documentation regarding the status of the patient's preference for a directive, but the documentation was in a location that was inaccessible after working hours. While this indicates the agencies have made some effort to document, documentation problems create situations where the wishes of the patient may not be followed, due to either the lack of or inaccessibility of information.

Pregnant women were the largest category of patients in the sample lacking documentation of directives in their medical charts. Of the 116 women in the sample with diagnoses of pregnancy or related to pregnancy, 41 had no documentation in their chart and 8 had notations stating "unknown" regarding the presence of an advance directive. Two facilities stated they did not give information to pregnant women, since provisions of advance directives were not applicable while a woman was pregnant. Other facilities

stated information was provided to pregnant women, but they could be missed, since they were often admitted through the emergency room or directly to the floor. Although many hospitals had a policy of following up, to determine if the patient had a directive, the information in the chart was often not updated to reflect the follow-up.

Many State laws indicate advance directives do not apply during a woman's pregnancy, if it appears that her baby may be able to go full term. However, the need to inform pregnant women of advance directives is still important. If a pregnant woman, not informed of her right to an advance directive, should experience a tragic outcome, her wishes regarding continued life support, after the delivery of the baby, would be unknown. This could be equivalent to denying the pregnant woman an opportunity to make decisions regarding her medical treatment, which was the intent of the provisions.

Another group of patients, whose charts frequently lacked clear documentation regarding advance directives, were those patients who were confused or very ill and were not accompanied by a friend or family member during admission. Without such assistance or counsel, it was difficult or impossible for the facility to obtain accurate information on patient's advance directive preferences.

In telephone interviews with individuals whose charts had been reviewed, several said they had a directive while the information in the chart did not indicate this. Thirteen individuals whose medical charts lacked any documentation, stated they had an advance directive prior to being admitted for care. In addition, 11 individuals with documentation that they did not have an advance directive, stated they did have one prior to being admitted. While there is no way of confirming this information, if true, it would be difficult to comply with these individuals' treatment wishes, due to either the lack or inaccuracy of documentation in the chart.

Problems In Clearly Documenting Patients' Charts May Result From the Lack of Guidelines on Acceptable Documentation.

All types of facilities included in the sample had some charts that did not clearly specify "yes" the patient has an advance directive or "no" the patient does not have an advance directive. Ambiguous documentation and documentation located outside of the patient's chart accounted for approximately five percent of the documentation efforts. When examining documentation by facility type, about one-fourth of nursing facility charts had documentation located outside of the charts and approximately four-and-a-half percent of hospital charts had "unknown" specified. In addition, a number of the over nine percent of hospital charts lacking any documentation were charts of pregnant women. In some facilities, personnel stated pregnant women were not asked whether they had a directive, as they understood the state law to specify directives were not applicable when a woman was pregnant. These results appear to indicate facilities are unsure of exactly what constitutes appropriate documentation of whether the patient does or does not have a directive.

Comments made by sample facilities support this finding[41]. One facility stated that the lack of specific documentation guidelines was a problem. In addition, personnel in many facilities inquired about the appropriateness of their documentation efforts during the chart review undertaken for the study. Some facilities mentioned problems clearly documenting the required information due to the patient's condition, admission of patients through the emergency room, clinics or after hours, and the difficulty in obtaining information for day surgery and short stay patients. Finally, some facilities mentioned the difficulty of obtaining clear information on advance directive preferences from confused or disoriented patients. In many of these cases, "unknown" or "comprehension poor" were noted.

Only 60 Percent Of The Patients With Advance Directives Had Copies Of The Directive In Their Medical Chart.

Of the charts with documentation (either in the chart or in the financial folder) indicating the patient has an advance directive, 57.5% have a copy of the directive in the chart. Approximately two-and-a-half percent of the charts with copies of advance directives did not have documentation in the chart stating the patient had a directive. A note was present in eight percent of the charts indicating where a copy of the advance directive could be found and 31.8 percent of the charts had neither a copy of the directive nor a note stating the location.

The lack of copies of advance directives in patient charts is acknowledged as a problem by many facilities. During discussions regarding facilities' problems or difficulties in implementing the advance directive provisions, 12 specified the difficulty in obtaining copies of the directive for placement in the chart. Problems in obtaining directives ranged from patients being requested to provide a copy of their directive but not doing so, patients not being able to obtain a copy due to lack of mobility and not wishing to give an original to the provider, patients not being aware that they should bring a copy of a directive to a facility upon commencing care, relatives having to be responsible for obtaining a copy or papers having to be sent out of State in order to obtain a copy of a directive from a relative.

TWENTY-ONE PERCENT OF PATIENTS RECEIVING CARE FROM HOSPITALS, NURSING FACILITIES, AND HOME HEALTH AGENCIES HAVE ADVANCE DIRECTIVES.

PATIENTS WITH ADVANCE DIRECTIVES*				
	Total With Directives	Average Age (sample)	Female	Male
All facilities	21.2%	73	55.5%	42.7%
Hospital	18.2%	63	48.3%	49.5%
Nursing Facility	47.7%	79	58.9%	40.2%
Home Health	25.1%	76	77.1%	22.3%

*--numbers may not sum to 100% due to missing sex and age information

Examination of the data indicates that nursing facility and female patients are more likely to have advance directives. The fact that a greater percentage of nursing facility patients have a directive is consistent with the common view that advance directives are documents that should be considered by people who may be approaching the end of their life.

Examination of individuals from the sample with directives, by age group and diagnoses, provided some additional insight into the public perception of advance directives. Nine percent of the patients under age 30, 11 percent of the patients between the ages of 36 and 45, and 20 percent of the patients between the ages 46 and 55 had a directive. The percentages continue to increase with age, with 34.7 percent of individuals over the age of 85 having a directive. The diagnoses among individuals having a directive included 10 percent with cancer, eight percent with a diagnosis of broken hip, seven percent with stroke and five percent having a diagnosis of congestive heart failure. While none of these diagnoses are exclusively related to the elderly, more older people tend to have these medical conditions. In addition, each of these has a higher likelihood of mortality than the other diagnoses in the sample.

The sample findings indicate the public tends to perceive advance directives as only being appropriate for the very old and very ill. This is further supported by comments made by interviewed individuals such as, "I was only having a baby," or "I am too young to think about that." Unfortunately, many of the legal cases which brought this issue to the attention of the public involved young people. These individuals met with tragic experiences resulting in the extended use of life-sustaining measures, beyond what their family members felt the individual would have wanted. These findings also support the need to provide public education on the topic of advance directives.

TWO THIRDS OF THE INDIVIDUALS INTERVIEWED HAD SOME UNDERSTANDING OF ADVANCE DIRECTIVES.

Percent of Individuals Interviewed With Understanding of Advance Directives				
Facility Type	Patient	Relative	Relevant Individual	Overall
All Types	63%	74%	89%	67.5%
Hospital	61%	77%	(not applicable)	64%
Nursing Facility	71%	71%	83%	72%
Home Health	60%	77%	100%	67%

Interviews were held with 348 individuals whose charts were randomly selected from each facility's original sample. Of the individuals interviewed, 130 were former patients, 209 were family members, and nine were friends, caretakers or lawyers. The interviews indicated that 235 of the individuals had some understanding of advance directives or related terms such as, living will, durable power of attorney for health care, proxy,

surrogate or patient advocate. Understanding was judged to be present if the individual could either give at least a simple definition of the term advance directive, living will or durable power of attorney, or if they volunteered information regarding their previous familiarity or experience with an advance directive.

It is noteworthy that patients as a group included the smallest percentage of respondents with an understanding of advance directives. Only nursing home patients demonstrated understanding equivalent to that of family members. Facilities reported patient understanding often is very poor upon admission, due to the anxiety surrounding their health condition and the number of papers presented to them. Reinforcing this point is the fact that 10 percent of patients who could not recall what an advance directive was mentioned they were too ill, too upset or were bombarded by too many papers at admission. Furthermore, 12 percent of individuals stated they did not remember receiving information on the topic, and 16 percent stated they did not receive information on advance directives upon admission. This supports the suggestion of 17 facilities that the provision of information on advance directives should begin before the patient is admitted for care.

Nursing facility patients had the highest understanding of advance directives among patient respondents. This might be a function of the generally long stays associated with nursing facilities which allow more time to explain and re-explain advance directives as necessary. It may also indicate that the average population in nursing homes, frail elderly people, have considered this topic prior to arriving at the nursing facility. Also, many individuals receiving care from a nursing facility may demonstrate greater knowledge and education on the topic because they view it as more relevant to their lives.

Of the individuals with understanding of advance directives, 186 could provide at least a simple definition of either "living will" or "durable power of attorney for health care" without prompting. A larger percentage recalled "living will." For example, 77 percent correctly defined a living will, while 55 percent defined a durable power of attorney for health care. Four percent of individuals provided an incorrect definition, although they thought they understood the term, and two percent of the individuals stated they had an advance directive, when they actually had a general or durable power of attorney with no health specifications.

Six facilities specifically mentioned the problem of patient difficulty in understanding the information due to the different terminology used, or the similarity between advance directive terms and other legal terms. Facilities also noted some patients confuse living wills with wills and confuse durable power of attorney for health care with a durable power of attorney related to financial areas. This concern was reinforced by some respondents who when asked to define the terms gave the definition of a will, or durable power of attorney for financial affairs. Eight facilities suggested using uniform language and simpler terms in an effort to encourage greater understanding of advance directives.

The need for a public information campaign by the Secretary of Health and Human Services, as called for in the legislation, was supported by comments made by facilities.

Many facilities cited the need to provide a greater opportunity for public education on the topic to improve patient understanding of advance directives. They also indicated that education should be provided at a variety of levels. Facilities cited early education in schools, providing information through large community and government organizations and using televised public service announcements as ways of reaching more people. Additionally, ten facilities felt physicians should be more involved in discussing this area, as they are generally the patient's initial contact with the health system.

We Found No Evidence Of Patients Being Pressured To Have Advance Directives.

A concern voiced by Congress and others before the advanced directive provisions were enacted was that patients would either feel that they were required to have a directive to obtain treatment or this would be subtly communicated to patients. In addition, there was concern that poorer or more disadvantaged patients might be encouraged to have a directive. Two steps were taken to examine this concern. First, we reviewed materials provided to the patient by each facility to see if a clear statement that a directive was not required was present. Second, in interviewing patients and family members we specifically asked if they had to have a directive to receive treatment. Our review showed 78 percent of the materials clearly stated that a patient was not required to have an advance directive to receive treatment. Similarly, our interviews detected only one person who felt they might have been required to have a directive to receive treatment. Finally, a review of the data indicated that Medicaid patients, generally poorer and more disadvantaged, consistently were the least likely to have a directive. This would indicate they were not more likely to be encouraged to have a directive when compared to other groups.

Only 32 Percent of the Facilities Provided Additional Information In Materials To Promote Patient Understanding Of And Comfort With Advance Directives.

An examination of facility efforts to alleviate the concern that patients might feel pressured to have an advance directive was also undertaken. This examination involved reviewing the content of advance directive materials provided to patients upon admission. To determine if facilities were clarifying that advance directives were not required in order to receive care, could be revoked at any time and should be carefully considered, we developed an index to examine facility efforts in communicating this information. This index was called the quality index. The quality index contained three items and was used to check whether materials provided to patients:

1. Mention the need to discuss treatment preferences with family and friends in case they should have to make medical decisions for the patient;
2. State the patient has a right to revoke the advance directive at any time; and
3. Advises patients that the facility has blank advance directive forms for their use upon request.

The data from sample facilities indicates there is a need to improve facility performance in providing information to increase patients' understanding and level of comfort with advance directives. For example, 22 percent of the facilities met none or only one of the three items and only 32 percent of facilities met all three indices. Once again, including these items in materials could increase patient understanding of advance directives, an area which facilities noted as needing improvement.

Percentage of Facilities Including Quality Information in Patient Materials				
Facilities	Quality Index Scores for Facilities			
	Zero	One	Two	Three
All Types	4.1%	18%	45.8%	31.9%
Hospitals	0	20.8%	54.1%	25.0%
Nursing Facilities	4.1%	16.6%	37.5%	41.6%
Home Health Agencies	8.3%	16.6%	45.8%	29.1%

Receiving Information On Advance Directives Appeared To Have Some Impact On Patients' Interest In Obtaining A Directive.

Being informed of the right to have an advance directive, and receiving information on the topic, did appear to influence some of the patients who were interviewed. Seventy-three, or 20.9 percent, of the individuals interviewed said they would consider getting a directive after hearing about them. In addition, 14 (or four percent of the individuals) actually executed a directive after receiving treatment.

This finding underscores the importance of discussing advance directives with patients before they become ill. The appropriate place to begin this process may be in the physician's office, since they are often the initial patient contact with the health care system. Once again, this lends support to the suggestion of ten facilities, that physicians become more involved in discussing advance directives with patients. Further, this finding also supports the need to provide general public education on the topic, to encourage people to both think about and discuss advance directives with relatives or friends.

RECOMMENDATIONS

While the majority of facilities reviewed have met many of the requirements of the advance directive provisions within the first five months of implementation, some areas of concern exist regarding:

- patient knowledge and understanding of advance directives
- facilities documentation of advance directives and
- the presence of the directive in the chart.

Because advance directives are a complicated topic not falling neatly into one arena, a coordinated effort should be considered in addressing these concerns. This effort should involve the State agencies and intermediaries involved with the Medicaid and Medicare program, as well as involved outside agencies. Assistance for facilities participating in the Medicaid or Medicare programs should also be available from the HCFA, the agency writing the Federal rules and regulations pertaining to the advance directive provisions. This would increase the potential for consistent interpretation of the requirements.

The coordinated effort should also include the Joint Commission for Accreditation of Health Organizations (JCAHO). Much of the determination of compliance with the provisions will be left to the JCAHO in facilities they accredit. While the JCAHO has specific review items pertaining to the provisions, including the presence of a directive in the chart, they do not include simple documentation of whether the patient has a directive. Since findings of this inspection indicate that 11 percent of patients with advance directives did not have this documented in their chart, and 20 percent of charts lacked clear documentation, support is present for a general documentation item. The lack of such documentation weakens the ability to both know and comply with patient wishes.

To assure patient participation in some of the most delicate issues confronted in health care, we make the following recommendations:

The HCFA should develop and issue specific regulatory guidelines clarifying acceptable documentation methods to assist providers in meeting the requirements of the Federal Statute. The guidelines could be incorporated in the Final Regulations which are currently pending, and should specifically address what constitutes acceptable documentation of whether a patient does or does not have a directive. Alternatively, the HCFA could disseminate documentation guidelines through other options:

- A program memorandum from HCFA to State Medicaid Agencies and Medicare Fiscal Intermediaries specifying documentation requirements.
- Medicaid Agencies and Medicare Intermediaries could provide a notification letter to all participating facilities on documentation requirements.
- Participating facilities could be informed of Medicaid and Medicare contacts who can provide technical assistance on specific documentation requirements.

The HCFA should encourage the JCAHO to examine if the medical record for each patient documents whether or not the patient has an advance directive. This would be in addition to the existing JCAHO review item regarding the presence of a copy of the advance directive in the chart.

The HCFA, along with other appropriate departmental offices, should provide leadership to develop a coordinated Department of Health and Human Service plan for educating the general public on advance directives.

The education plan should 1) address the statutory requirement for the Secretary to lead a national public information campaign on this topic, 2) incorporate a variety of means for conveying the message in a cost-effective manner and 3) should involve all appropriate DHHS components (The Social Security Administration (SSA), The Public Health Service (PHS), The Administration On Aging (AOA), The Administration For Children and Families (ACF), The Assistant Secretary for Public Affairs (ASPA), etc.). Options for developing a public education plan might include:

- A public information campaign to increase understanding of advance directives which could include:
  - Encouraging the development of Public Service Announcements regarding advance directives. The department could consider providing such announcements in conjunction with national organizations of health care providers or advocacy groups.
  - Encouraging professional organizations to provide community education on the topic in conjunction with local health care facilities.
  - Developing generic informational materials which could be provided to a variety of agencies.

- A coordinated effort involving all relevant agencies to provide uniform information on advance directives to individuals receiving program services or benefits from the HCFA, SSA, PHS, AOA, ACF, and the ASPA. Generic information, such as that included in the 1993 Medicare Handbook, could be used by other agencies in booklets, public materials and mass mailings.

- Encouraging coordinated State and private efforts to provide the public with a means of carrying information on their person to alert physicians or facilities that they have an advance directive including:
  - Investigating the possibility of a check-off box on driver's licenses for individuals with advance directives, in conjunction with the State Motor Vehicle Departments.
  - Discussing the development of bracelets or neck chains, similar to those available to people with specific health conditions, to indicate an individual has an advance directive, with various groups whose purposes are to promote health/medical awareness and provide public information.

SUMMARY OF AGENCY COMMENTS AND OIG RESPONSE

We solicited and received comments from the HCFA on the draft report. The complete text of the HCFA comments are contained in Appendix C.

The HCFA concurred with our recommendation to provide leadership in educating the public on advance directives, but suggested that the Assistant Secretary for Public Affairs (ASPA) take the lead role in coordinating this effort. The HCFA also concurred with our recommendation to work with JCAHO to include a specific review item to determine the presence of documentation in the medical record that indicates whether or not a patient has executed an advance directive. However, based on conversations with JCAHO, the HCFA believes this item has been addressed in the accreditation process. The HCFA did not concur with our recommendation to develop more specific guidance on chart documentation, expressing concerns that such guidance might be overly prescriptive and reduce provider flexibility.

While we appreciate HCFA's concerns about overly prescriptive guidance, we continue to believe that additional guidance is needed. Although we believe that HCFA's interim final rule will assist facilities in complying with the law, some questions still remain. We found several situations in which it might be difficult to document whether or not patients had executed an advance directive. For example, some patients' mental status may not allow them to provide the needed information upon admission and they may not be accompanied by an individual who is knowledgeable about their personal affairs. In other situations, State laws may lead to misunderstandings regarding the need to collect this information. For example some hospitals, in States where an advance directive may not be implemented during a woman's pregnancy, do not even ask pregnant women whether or not they have an advance directive when they are admitted. In still other circumstances, nonstandard or emergency admissions may create problems in obtaining the necessary information. For example, when individuals are admitted either after hours or directly to a hospital unit they often bypass the process for obtaining information on advance directives. We believe that more specific guidance would help facilities handle these situations and comply with the statute. This guidance need not be any more prescriptive than the guidance already contained in the interim final rule, but would only be more expansive in requiring that these subjects be addressed along with other topics.

Based upon HCFA's comments regarding our recommendation on JCAHO reviews, we have revised the wording of our recommendation. It was our intent to recommend that JCAHO, in their review of a sample of medical records, examine the records for documentation of whether or not patients have executed an advance directive, in addition to their current review of whether an advance directive is present in the chart. As HCFA states, currently the JCAHO reviews medical records to determine only if an advance directive is present in the chart, an item that is not a Federal requirement. In contrast, the Federal statute requires that facilities "document...whether or not the individual has executed an advance directive." The absence of an advance directive may indicate a number of possible scenarios. It may indicate that an individual does not wish to execute an advance directive, or that an individual was not informed that s/he has a right to have

an advance directive or that an individual has an advance directive but a copy has not been placed in the medical record. In fact, our study shows that 40 percent of persons with advance directives fell into this latter category. We believe that a specific documentation requirement to indicate whether or not an advance directive was executed, as the statute requires, would better ensure that medical records contain meaningful information about a patient's decision concerning an advance directive. Such documentation would also better ensure that a patient's wishes are known to providers when making treatment decisions.

We support the HCFA's suggestion that other appropriate departmental members should participate in the public education effort on advance directives. However, because primary authority for the advance directive provisions lies with the HCFA, and they have established relationships with the providers affected by the provision, we feel the HCFA should be responsible for negotiating with the suggested departmental components, including ASPA, to decide who should coordinate and participate in this campaign. We have revised our recommendation accordingly.

The HCFA also raised questions concerning:

- whether we had reviewed facilities' compliance too early in the process;

- whether the reason for lack of documentation in medical charts arose from lack of understanding of State laws, the patient's condition, or the mode of admission, rather than confusion about what constitutes acceptable documentation; and

- whether the low level of documentation we found is consistent with our statement that most facilities are complying with legislative requirements.

We recognize that we have reviewed facilities' compliance with the statute 4 to 5 months after the effective date, and 1 month after HCFA issued its draft regulations. It was indeed our intent to present information on facilities' experiences and efforts as they first began to implement the statute's requirements. While it is logical to assume that compliance increases with experience and knowledge on the part of providers, some of the problems that arise in the early stages of implementation--if addressed quickly--can best ensure smooth realization of new requirements over time. Additionally, we also recognize that the HCFA issued Program Memoranda in October and December of 1991 to inform all facilities and State Agencies of the requirement to implement the self determination legislation by December 1, 1992.

Based on HCFA's comments regarding the possibility that factors other than confusion about acceptable documentation might have contributed to poor documentation, we have refined our sub-finding on this point.

Finally, we appreciate HCFA's point about whether facilities are generally complying with legislative requirements if they are not meeting documentation requirements. However, we indicate that in our review, facilities were in fact complying with many aspects of the

legislation, with the requirement regarding documentation being the most obvious exception. It is for this reason that these issues were separated and our first two recommendations are directed at strengthening guidance and technical assistance in this area.

ENDNOTES

1. The advance directive provisions were enacted as Sections 4206 and 4751 of the Omnibus Budget Reconciliation Act of 1990, Public Law 101-508. The original bill, referred to as the Patient Self Determination Act, was introduced as S. 1766 by Senators Danforth and Moynihan and H.R. 5067 by Congressman Sander Levin.

2. Levin, Sander, D. MI, Remarks in the House of Representatives on H.R. 5067: Patient Self-Determination, Thursday, Jun 28, 1990, CR page E-2190.

3. McCloskey, Elizabeth Leibold, "The Spirit of the PSDA", *Practicing the PSDA*, Hastings Center, Sept-Oct 1991, pg S14.

4. Rouse, Fenella, "Patients, Providers, and the PSDA", *Practicing the PSDA*, Hastings Center Report, Sept-Oct 1991, pg S2.

5. Rouse, Fenella, ibid.

6. McCloskey, Elizabeth, "The Patient Self-Determination Act", *Kennedy Institute of Ethics Journal*, I, no. 2, 1991, pg 163-69.

7. OBRA 1990, P.L. 101-508, section 4206, Conference agreement, pg. 129.

8. Rouse, Fenella, ibid.

9. Nancy Beth Cruzan, by her Parents and Co-Guardians, Lester L. Cruzan, et ux, Petitioners V Director, Missouri Department of Health, et al., U.S. Supreme Court Reports, 1990, 497 US -, 111 L Ed 2d 224, 110 S Ct-, no. 88-1503.

10. Legislative History, House Report No. 101-881, sec. 4122, pg. 88.

11. Bedell, Susanna E., and Delbanco, Thomas L., "Choices About Cardiopulmonary Resuscitation in the Hospital, When Do Physicians Talk With Patients?", *The New England Journal of Medicine*, 1984, Vol 310, no. 17, pgs. 1089-1093.

12. Jonsson, McNamee, and Campion, "The 'Do Not Resuscitate Order' A Profile of Its Changing Use," *Archives of Internal Medicine*, Nov 1988 pg. 2373.

13. Bedell, Susanna E. et al., "Do Not Resuscitate Orders for Critically Ill Patients in the Hospital, How Are They Used and What is Their Impact", *Journal of the American Medical Association*, July 1986, vol. 256, no.2, pgs 233-237.

14. Bedell & Delbanco, ibid.

15. Jonsson, McNamee, & Campion, ibid.

16. Bedell et al., Ibid.

17. Uhlmann, Richard F., et al., "Physicians and Spouses Predictions of Elderly Patients Resuscitation Preferences", *Journal of Gerontology*, 1988, Vol 43, no. 5, M115-121.

18. Ouslander, Joseph, et al., "Health Care Decisions Among Elderly Long-term Care Residents and Their Potential Proxies", *Archives of Internal Medicine*, June 1989, vol 149, pgs 1367-1372.

19. Uhlmann, et al., Ibid.

20. Ouslander, et al., Ibid.

21. Emanuel, Linda and Barry, Michael, et al., "Advance Directives For Medical Care -- A Case For Greater Use", *The New England Journal of Medicine*, Vol 324, No. 13, pgs. 889-895.

22. *The Right To Die*: Times Mirror Center for the People and the Press, 1990,

23. Emanuel, & Barry, ibid.

24. McCrary, Van and Botkin, Jeffrey, "Hospital Policy on Advance Directives, Do Institutions Ask Patients About Living Wills?", *Journal of the American Medical Association*, Nov. 1989, vol 262, no. 17, pgs 2411-2414.

25. McCrary, ibid.

26. McCrary, ibid.

27. Kamer, R.S., et al., "Effect of New York States Do Not Resuscitate Legislation On In Hospital Cardiopulmonary Resuscitation Practice", *American Journal of Medicine*, 1990, vol 88, pgs. 108-111.

28. Tarnowski, K.J., et al., "Readability of Pediatric Biomedical Research Informed Consent Forms", *Pediatrics*, 1990, vol 85, pgs. 58-62.

29. Berman H, Rose L., *Choosing the Right Health Care Plan*, Mount Vernon N.Y.1, Consumers Union, 1990, 3.

30. Annas, George J., "The Health Care Proxy and the Living Will", *The New England Journal of Medicine*, April 1991, vol 324, no.l 17, pgs. 1210-1213.

31. La Puma, John, et al., "Advance Directives on Admission, Clinical Implications and Analysis of the Patient Self-Determination Act of 1990", *Journal of the American Medical Association*, July 1991, Vol 266, no. 3, pgs. 402-405.

32. La Puma, et al, ibid.

33. La Puma, et al, ibid.

34. White, Margot and Fletcher, John, "The Patient Self Determination Act, On Balance, More Help Than Hindrance (editorial)", *Journal of the American Medical Association*, July 1991, vol. 266, no. 3, pgs 410-412.

35. Puma, et al., "In Reply to Letter to the Editor", *Journal of the American Medical Association*, Dec 1991, vol. 266, vol. 24, pg. 3424.

36. White & Fletcher, ibid.

37. While individual State Laws regarding advanced directives were not reviewed, information prepared by Charles Sabatino of the Commission on Legal Problems of the Elderly within the American Bar Association (September 1991), Amy Rosenberg, Editor for the AAHA Legal Memo within the American Association of Homes for the Aging (Summer 1991) and a draft article for Clearing House Review (October 1991) by Charles P. Sabatino and Vicki Gottlich, "Seeking Self Determination in the Patient Self-Determination Act," were used as a guide to State Legislation on the topic.

38. For initial sample selection, States were grouped strictly on the basis of existing legislation, although legal opinions and case law may also be considered when determining the types of advance directives allowed in each State. Based on this selection approach, one State, Nebraska, was excluded from the sample due to lack of legislation pertaining to advanced directives at the time of the study. Two additional States, Alaska and Hawaii, were excluded from the sample due to their distance and cost considerations. Although Maryland did have an Attorney General's opinion recognizing the legal effectiveness of the Durable Power of Attorney for Health Care, this opinion did not appear in Statute. Thus, the DPAHC in Maryland was not considered for grouping purposes. Only the living will was considered for grouping purposes. Washington has legislation regarding both living wills and DPAHC, and thus was grouped based on this information. However, the legislation regarding DPAHC is very limited, allowing a named individual to only provide informed consent for those treatment decisions previously specified by a patient. Because both types of directives did appear in statute, Washington was grouped based on the presence of both types of advance directives, despite the limits placed on the DPAHC. Finally, at the time of the study design, Arizona was characterized as having only a living will statute and was grouped based on this information. However, at time of data collection it was noted that information was provided to patients on both living wills and DPAHC. Upon further clarification from David Landreth of the Arizona Medical Association, it was determined that Arizona enacted a DPAHC statute during the summer of 1992, and both living wills and DPAHC are now officially recognized. For purposes of this study, the sample States selected were categorized as follows: 1) Florida and Washington, living will and DPAHC, 2) Maryland and Arizona, living will, and 3) Massachusetts and Michigan, DPAHC.

39. The legislative index developed for use in this study was based on information provided in Public Law 101-508, section 4206, 1990 Budget Reconciliation, the draft interim rule, referred to in this report as draft regulations dated February 6, 1992, the

Program Memorandum to Intermediaries dated December 1991, Program Memorandum to Medicaid State Agencies dated October, 1991, and information on page 2 number 690 of the Medicare and Medicaid Guide in the discussion of the issuance of the interim final rule on advanced directives. All six of the items are specifically mentioned in the requirements and have been assigned the same weight of one. An additional item was clearly mentioned in the requirements, the need to document in the patient's medical record whether or not they have a directive. Since data on this specific item was collected and discussed at length in other sections of this report, it was not included in the legislative index.

40. Since the design of this study and the collection of the data, an additional item has been clarified specifically as a requirement in complying with legislation on advanced directives. This information was provided in the Medicare Hospital Manual, transmittal number 641, date August 1992. The additional requirement is noted in parentheses on page 134 of the Medicare Hospital Manual. The requirement specifies that facilities must provide written information to the patients regarding any conscientious objection clause the facility might have regarding implementing advanced directives, to the extent it is allowed in State law. A conscientious objection clause refers to the ability of the hospital or any agent of the hospital to refuse to implement a directive as a matter of conscience.

41. After the data collection for this inspection had been completed a hospital in Michigan contacted the project leader about the chart documentation issue. The individual calling was responsible for the Medical Records function in the hospital. She stated other individuals with this responsibility in Michigan hospitals had expressed their concerns about appropriate documentation in the charts of patients during discussions. She stated one of the individuals involved in the discussion worked in a hospital that had been included in the sample for this inspection, prompting her call. She wanted to express her interest in seeking guidance on documentation. She was referred to individuals in her regional office and HCFA. This indicates that other facilities have specific concerns about documentation issues.

APPENDICES

Appendix A Regression Results

Appendix B Weighted and Unweighted Chart Data

Appendix C Full Text of Agency Comments

APPENDIX A

Regression analysis on the sample data was undertaken estimating two models. The dependent variable was the percent of charts in each facility with clear documentation stating whether or not the patient has an advance directive. Our regression analysis detected five factors (independent variables) that were statistically significant:

1) status as a for-profit organization,
2) the lack of staff education or documentation of staff education on the topic,
3) the provision of staff education after the Act was implemented,
4) location in the State of Florida, and
5) the provider was a nursing home.

There was no significant effect of whether the provider was a hospital or home health agency, location in one of the other sample States, or from having a higher score on the administrative index. See Table 1 for regression results.

The effect of status as a for-profit organization was positive in both models, meaning they were more likely to have a larger percentage of charts with documentation present when compared to not-for-profit facilities. In the second equation where States were controlled, this variable had the greatest impact. As many of the for-profit agencies were members of a multiple facility system, this could indicate efficiencies in central development and dissemination of information. This may allow the facilities in for-profit multi-facility systems to have more standardized procedures and forms which could impact the documentation in patient charts.

The effects of both lack of staff education or having no documentation that education was provided and providing education after the Act became effective were negative in both models. This indicated that the facilities which provided education after the requirements were implemented, had a lower percentage of charts with documentation present than did facilities which provided education before the implementation of the Act. The staff education variables had the greatest effect of the significant factors in the first regression model. This could indicate that the education did affect employee awareness and attention to this new procedure, and reinforces the importance of the education requirement. It could also indicate that facilities that document, document well.

In model two, variables were included to account for the effect of each State. When controlling for each State in the sample, the effect of a facility located in the State of Florida was negative and significant when compared to the omitted category (which was Washington). Location in any of the other sample States did not result in any significant changes. This indicated that facilities in Florida had a lower percentage of charts with documentation present. In addition, when controlling for States in the sample, the effect of whether the provider was a nursing home became statistically significant and negative. This indicated that nursing facilities were more likely to have a lower percentage of charts with documentation present when compared to hospitals, after looking at individual States.

Table 1

REGRESSION RESULTS: *Percent of Charts in Facility With Documentation*

Independent Variable	(Model 1) Percent Chart Compliance Per Facility	(Model 2) Percent Chart Compliance Per Facility
INDEX	8.77	5.18
	(5.29)	(5.67)
For Profit	8.82*	12.75**
	(4.12)	(4.28)
Public	6.15	4.49
	(5.13)	(4.97)
Nursing Facility	-7.46	-9.05*
	(4.37)	(4.15)
Home Health Agency	-2.84	-3.82
	(2.91)	(2.77)
Ed After Implementation	-10.85**	-8.08*
	(3.83)	(3.73)
No Education	-10.38*	-11.35**
	(3.96)	(3.85)
Arizona		1.21
		(6.00)
Florida		-9.36*
		(4.00)
Massachusetts		-3.35
		(2.81)
Maryland		.56
		(2.33)
Michigan		1.91
		(2.05)
Constant	24.78	38.21
R Square	.220	.366
Adjusted R Square	.135	.238
F =	2.585*	2.84**

* = sig. .05 ** = sig. .01
(standard error presented in Parentheses)

APPENDIX B

WEIGHTED AND UNWEIGHTED CHART DATA REPORTED IN THE TEXT

STATUS OF DOCUMENTATION IN PATIENTS MEDICAL RECORD: Sample/Weighted					
Facility Type	Documented in Chart	Not Documented in Chart	Documented, But Filed Elsewhere	"Unknown" noted in Chart	Unable to Comprehend Noted in Chart
All Types	76.0%/80.5%	18.0%/14.0%	3.2%/1.7%	1.7%/3.3%	1.1%/.2%
Hospitals	81.7%/86.2%	14.2%/9.4%	0	4.1%/4.4%	0
Nursing Facilities	69.1%/46.0%	16.0%/25.5%	12.0%/26.7%	0	2.8%/1.8%
Home Health	74.7%/68.0%	23.8%/31.5%	0	.5%/.03%	1.0%/.5%

PATIENTS WITH ADVANCE DIRECTIVES: Sample/Weighted*				
Type of Facility	Total Patients With Advance Directives	Average Age (sample)	Female	Male
All Facilities	26.6%/21.2%	73	64.1%/55.5%	35.9%42.7%
Hospital	20.8%/18.2%	63	60.6%/48.3%	39.1%/49.5%
Nursing Facility	40.3%/47.7%	79	67.8%/58.9%	32.1%/40.2%
Home Health	22.4%/25.1%	76	62.1%/77.1%	37.8%/22.3%

*--numbers may not sum to 100% due to missing sex and age information

APPENDIX C

AGENCY COMMENTS:
HEALTH CARE FINANCING ADMINISTRATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE JUN 30 1993

FROM Bruce C. Vladeck
Administrator

SUBJECT Office of Inspector General (OIG) Draft Reports: "Early Implementation of the Patient Self-Determination Act" (OEI-06-91-01130), and "Facility and Patient Responses to the Patient Self-Determination Act" (OEI-06-91-01131)

TO Bryan B. Mitchell
Principal Deputy Inspector General

We have reviewed the draft reports which present OIG findings on the extent of institutional compliance with the advance directive provisions of the Omnibus Budget Reconciliation Act of 1990 and patients' understanding of their rights and information provided to them in regard to this provision. Our specific comments are attached for your consideration.

Thank you for the opportunity to review and comment on these reports. Please advise us if you agree with our position on the report's recommendations at your earliest convenience.

Attachment

Comments of the Health Care Financing Administration (HCFA) on
the Office of Inspector General (OIG) Draft Reports:
Early Implementation of the Patient Self-Determination Act,
(OEI-06-91-01130),
and
Facility and Patient Responses to the Patient Self-Determination Act,
(OEI-06-91-01131)

Recommendation 1

The HCFA should develop and issue specific regulatory guidelines clarifying acceptable documentation practices to meet requirements of the Patient Self-Determination Act. Guidelines could be incorporated in the Final Regulations which are currently pending and specifically address what constitutes acceptable documentation of whether a patient does or does not have a directive. The HCFA could further disseminate documentation guidelines in the manner used in disseminating initial information on the requirements. For example:

- Program memorandum from HCFA could be provided to State Medicaid agencies and State Medicare fiscal intermediaries on specific documentation requirements.

- Medicaid agencies and Medicare intermediaries could provide a letter to all participating facilities on documentation requirements.

- Participating facilities should be informed of Medicaid and Medicare contacts who can provide technical assistance on specific documentation requirements.

HCFA Response

HCFA nonconcurs. We do not believe that it is prudent to be overly perscriptive in this area. Existing Medicare and Medicaid regulations include specific requirements governing medical record documentation. Hospital medical records standards (42 CFR 482.24) require the record to be accurate, legible, complete, and authenticated. If the records this study identified as ambiguous had been properly authenticated, staff could easily have contacted the author for clarification. HCFA regulations also include medical records requirements for nursing facilities [42 CFR 483.75(1): Records must be in accordance with accepted professional standards, complete, accurately documented, and readily accessible], and home health agencies [42 CFR 484.48: Records must be in accordance with accepted professional standards]. We believe these requirements are sufficient to accomodate

the advance directive requirement; therefore, we do not agree that specific regulatory guidelines are needed. If these facilities are not meeting existing standards, promulgation of new standards will not solve the problem.

The interim final regulation stated that there may be various ways to effectively obtain the information needed to document the medical record, but did not address the specifics of how this documentation should be done. The flexibility contained in our regulation is appropriate because it encourages innovation and avoids potentially unnecessary recordkeeping burden. We believe the focus should be on ensuring that providers comply with the documentation requirement, instead of prescribing the method for documenting the existence of an advance directive. Additionally, while we understand that many providers will collect copies of advance directives, we do not believe that the statute authorizes a regulatory requirement to do so.

The OIG study notes that the Joint Commission for Accreditation of Health Organizations (JCAHO) requires that any advance directive be included in the patient's chart. We would also like to point out that the States also typically include records requirements among conditions for licensure for health facilities. It appears that the report did not review the content of State advanced directive laws. These laws may contain additional documentation requirements.

Recommendation 2

HCFA should encourage the JCAHO to include a specific review item to determine the presence of documentation of advance directives in each patient's chart, in addition to the existing review items regarding directives.

HCFA Response

HCFA concurs to the extent that JCAHO agrees to any additional information collection requirement. It is a longstanding practice between HCFA and JCAHO to coordinate efforts, where possible, on the rules and regulations issued by each. We have had discussions with the JCAHO regarding advance directive rules and the documentation of such in the medical records, and it appears that they have addressed this issue. Specifically, the JCAHO's Accreditation Manual for Hospitals, standard RI.1.1.3.2.3., states that "any advance directive(s) is in the patient's medical record . . ." and the scoring process includes review of medical records.

Recommendation 3

The HCFA should provide leadership in developing a coordinated Department of Health and Human Services plan for educating the general public on advance directives.

HCFA Response

HCFA concurs. We recognize that additional work remains in educating the general public on advance directives and that HCFA should play a key role in developing a coordinated plan for carrying out that educational activity. Since this effort will involve several agencies within the Department, we believe responsibility for this action should rest with the Office of the Assistant Secretary for Public Affairs (OASPA), in order that tasks can be directed through the Department's chain of command. HCFA is nevertheless willing to provide staff support in working closely with the OASPA in carrying out this activity.

Technical Comments

We believe it is contradictory to assert that most facilities are complying with the legislative requirements, but at the same time find that only 26 percent of facilities clearly and consistently document whether the patient has an advance directive. Significantly, this report measured initial implementation efforts only 1 month after the regulation was in place.

On page 5, the report notes that some of the samples "have poor precision" due to the small number of samples, but concludes that "it is still felt that they represent a reasonable estimate of initial implementation efforts." Further explanation of this conclusion would strengthen the report, particularly in light of the contradictory findings in the Facility and Patient Responses report.

Most of the findings cited in the section entitled "Lack of Guidelines" of the Early Implementation of the Patient Self-Determination Act report (pages 10 and 11) do not support the section's conclusion. These findings indicate that facilities failed to document whether an advanced directive existed because personnel did not understand State laws, because of a patient's condition, or because the patient was admitted after hours or through the emergency room -- not due to confusion regarding what constitutes acceptable documentation. The Facility and Patient Responses report also indicates that the condition of the patient and the circumstances of admission were the reasons given for lack of documentation.

Marginal notes have been added to your draft report. A copy is attached.