TABLE 1.—INDUSTRIES AFFECTED BY LABELING REGULATIONS

SIC	Industry name	(Phase I regulations) Standard foods, ingredients, and colors labeling	(Phase I regulations) Percent juice labeling	(Phase I regulations) Raw fruit, vegetables, and fish labeling	(Phase II regulations) Mandatory nutrition labeling, format, nutrient content claims
*	* * * *	*	*	*	
2099	Food preparations, nec [1]	X		X	X
2834	Dietary supplements				X
5411–99	Grocery stores			X	

[1] Not elsewhere classified.

2. On page 60871, Table 13, is corrected to read as follows:

TABLE 13.—ESTIMATED HEALTH EFFECTS [1] (OVER 20 YEARS)

	Cases avoided or life-years gained	Total annual cases
Cancer	35,179	500,000
CHD	4,028	514,000
Deaths avoided	12,902	
Life-years gained	80,930	

[1] Uses lagtimes of 2 and 10 years for the occurrence of CHD and cancer, respectively following a diet change.

3. On page 60871, in column 2, Table 14, the entry "Prostate cancer" is corrected to read "Prostate/breast cancer".

4. On page 60876, in column 2, in the last paragraph, line 5, "3.6 billion" is corrected to read "between $3.6 billion and $21 billion".

Dated: February 21, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92–4729 Filed 3–5–92; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 101

[Docket No. 91N–0344]

RIN 0905–AD08

Food Labeling; Use of Nutrient Content Claims for Butter; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction

SUMMARY: The Food and Drug Administration (FDA) is correcting a proposed rule that would permit the use of nutrient content claims ("descriptors") that are defined by regulations in 21 CFR part 101 to be made for butter (November 27, 1991, 56 FR 60523). The document was published with some editorial errors. This document corrects those errors.

DATES Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFF–414), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–485–0112.

In FR Doc. 91–27158, appearing on page 60523 in the **Federal Register** of Wednesday, November 27, 1991, the following correction is made:

On page 60525, in the first column, in the last paragraph, line 1, "(3)(b)(1)(a)(viii)" is corrected to read "(3)(b)(1)(A)(viii)"; and in the third column, in the first paragraph, in the fourth line from the bottom, quotation marks are added before the word "Contains".

Dated: February 21, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92–4730 Filed 3–5–92; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Parts 5, 101, and 105

[Docket No. 91N–0384]

RIN 0905–AD08

Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that proposed to provide general principles and definitions for nutrient content claims and to provide for their use on food labels that appeared in the **Federal Register** of November 27, 1991 (56 FR 60421). The document was published with some editorial errors. This document corrects those errors.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may be issued based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF–312), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–485–0229.

In FR Doc. 91–27150, appearing at page 60421, in the **Federal Register** of Wednesday, November 27, 1991, the following corrections are made:

1. On page 60424, in the second column, in line 21, "§ 101.13(a)" is corrected to read "§ 101.13(b)(3)".

2. On page 60425, in the first column, in the second full paragraph, in the third line from the bottom, "§ 101.13(a)(1)" is corrected to read "§ 101.13(g)(1)".

3. On page 60428, in the first column, in the fifth paragraph, the last sentence in the quoted material is corrected to read "In addition, section 403(a) of the act will continue to prohibit brand names that constitute false and misleading labeling, irrespective of whether the brand name was exempt under this provision."

4. On page 60429, in the first column, in line 4, the word " 'low." is corrected to read " 'low' "; in the second column, in the third full paragraph, in line 1, "section IV" is corrected to read "section V".

5. On page 60431, in the second column, in line 10, "0.5 g" is corrected to read "0.3 g"; and in the first full paragraph, line 11, "§ 101.62(d)(1)(i)(8))" is corrected to read "§ 101.62(d)(1)(i)(B))".

6. On page 60433, in the first column, in the third full paragraph, in line 11, "§ 101.60(b)(1)(ii)" is corrected to read "§ 101.61(b)(1)(iii)"; and in the second column, in the second full paragraph, in line 2, the words "to allow" are removed.

7. On page 60436, in the second column, in the second full paragraph, in line 11, "§ 101.60(c)" is corrected to read "§ 101.60(c)(1)".

8. On page 60437, in the first column, in the second full paragraph, in line 6, "§ 101.60(c)(1)(i)" is corrected to read "§ 101.60(c)(1)(ii)"; in the second column, in the third full paragraph, in line 11, the words " 'sugar free,' " are corrected to read "'sugars free' "; in the third column, in the first full paragraph, the second and third sentences are removed; and in the second full paragraph, lines 3 and 4 are corrected to read "stated its position concerning the term 'no sucrose,' saying that its".

9. On page 60439, in the first column, in the second full paragraph, in line 9, "(Ref. 33)" is corrected to read "Ref. 26)".

10. On page 60441, in the first column, in line 1, "§ 101.61(b)(4)(iii)" is corrected to read "§ 101.61(b)(4)(ii)"; in line 17, "§ 101.61(b)(2)(iii)" is corrected to read "§ 101.61(b)(2)(ii)"; in the third column, in the third full paragraph, in line 2, "§ 101.61(b)(2)(ii)" is corrected to read "§ 101.61(b)(2)(i)"; and in line 6, "§ 101.61(b)(4)(ii)" is corrected to read "§ 101.61(b)(4)(i)".

11. On page 60442, in the first column, in the second full paragraph, in line 15, "§ 105.66(c)(1)(i)" is corrected to read "§ 105.66(c)(1)(ii)".

12. On page 60447, in the first column, in the first full paragraph, in line 5, the word "changes" is corrected to read "claims"; in the third full paragraph, in line 2, "§ 101.13(j)(2)(iii)" is corrected to read "§ 101.13(j)(3)"; and in the second column, in the second full paragraph, in the second line from the bottom, the words "of the 1990 amendments" are added before the word "requires".

13. On page 60452, in the third column, in the fourth paragraph, in line 8, the word "sugar" is corrected to "sugars".

14. On page 60454, in the third column, in the second full paragraph, beginning in line 5, the words "that .reduced' and 'light." are corrected to read "that 'reduced' and 'light' "; and in the fourth full paragraph, in the last line, "201(a)" is corrected to read "201(n)".

15. On page 60457, in the first column, in the first paragraph, in the last line, the calculation reading "4.75×2.8=13.5 g.)" is corrected to read "4.75 (19 percent of the DRV) × 2.8=13.5 g.)".

16. On page 60459, in the third column, in the second full paragraph, in line 2, the words "in pursuing this end" are removed; and in line 12, "3(b)(2)(A)(iii)" is corrected "3(b)(1)(A)(iii)".

17. On page 60460, in the second column, in the fifth full paragraph, in line 2, the words "of the act" are added before the word "requires"; and in the third column, in the first full paragraph, in line 14, the word "etitioner" is corrected to read "petitioner".

18. On page 60461, in the third column, in the first full paragraph, in line 7, the word "nsleading" is corrected to read "misleading".

19. On page 60466, in the second column, in the first full paragraph, in line 1, the word "foods" is added after "ESL".

20. On page 60468, in the third column, in Reference 9, add "*Journal of Nutrition Education*" before "p. 51"; and in Reference 16, "Virginia Wilkening, February 12, 1991" is corrected to read "J. S. Benson, July 11, 1990."

21. On page 60469, in the first column, Reference 26 is corrected to read as follows:

26. Joint Food and Agriculture Organization/World Health Organization Food Standards Program, "Codex Standards For Foods For Special Dietary Uses Including Foods For Infants And Children And Related Code of Hygienic Practice," Codex Alimentarius Commission, Vol. IX, 1st ed., p.3, Rome, 1982.

22. On the same page, in the first column, in Reference 36, in line 3, the word "Service" is corrected to read "Serving"; in the second column, in Reference 46, in line 1, "0708" is corrected to read "070B"; and in Reference 52, in line 1, the word "Ledding" is corrected to read "Lidding".

§ 101.13 [Corrected]

23. On page 60470, in § 101.13 *Nutrient content claims—general principles*, in paragraph (j)(2)(i), in line 4, the word "labeling" is corrected to read "label" the first time it appears; in paragraph (j)(2)(iii), in line 1, "(iii)" is corrected to read "(3)"; on page 60471, in column 1, in paragraph (n), in line 2, the word "claim" is corrected to read "claims" and in line 4, the word "the" is added before the word "analytical"; and in paragraph (o)(7), in the last line, "§ 101.50(h)" is corrected to read "§ 101.69(o)".

§ 101.54 [Corrected]

24. On page 60471, in § 101.54 *Nutrient content claims for "source," "high," and "more"*, in paragraph (c)(1), beginning on line 7, the phrase "of the (RDI) or the (DRV)" is corrected to read "of the RDI or the DRV".

§ 101.60 [Corrected]

25. On page 60473, in § 101.60 *Nutrient content claims for the calorie content of foods*, in paragraph (b)(2) introductory text, in the last line, "§ 101.13(1)" is corrected to read "§ 101.13(l)"; in paragraph (b)(3) introductory text, in line 4, "§ 101.13(1)" is corrected to read "§ 101.13(l)"; in paragraph (b)(4), beginning in line 3, the phrase "to describe a food, except mealtype products as defined in § 101.13(1)" is corrected to read "on the label or labeling of a food, except meal-type products as defined in § 101.13(l)"; in paragraph (b)(5), the phrase "including meal type products as defined in § 101.13(1)," is corrected to read "except meal-type products as defined in § 101.13(l),"; and paragraph (b)(6), which was inadvertently omitted is added to read as follows:

(6) A comparative claim using the term "fewer" may be used on the label or labeling of meal-type products as defined in § 101.13(l), provided that:

(i) The product contains at least 25 percent fewer calories, with a minimum reduction of more than 105 calories per

reference amount customarily consumed, where appropriate, and per labeled serving size, than the reference food that it resembles and for which it substitutes as defined in §101.13(j)(1)(i), (j)(1)(ii), and (j)(1)(iii); and

(ii) Meets the requirements of paragraph (b)(5)(ii) of this section.

26. On the same page, the heading for paragraph (c)(1) is corrected to read as follows:

(c) * * * (1) *Use of terms such as "sugars free," "free of sugars," "no sugars," "zero sugars," "trivial source of sugars," "negligible source of sugars," or "dietarily insignificant source of sugars."*

27. On the same page, in paragraph (c)(4), in line 3, the word "meal type" is corrected to read "meal-type".

§ 101.61 [Corrected]

28. On page 60474, in § 101.61 *Nutrient content claims for the sodium content of foods*, in paragraph (b)(1)(ii), the word "sodium" is corrected to read "salt" the first time it appears; in paragraph (b)(2) introductory text, in line 4, the word "mealtype" is corrected to read "meal-type".

§ 101.69 [Corrected]

29. On page 60475, in § 101.69 *Petitions for nutrient content claims*, in paragraph (m)(3), in the second line from the bottom, "paragraph (e)" is corrected to read "paragraph (g)"; and on page 60476, in paragraph (n)(1), in paragraph "B.", in line 5, the word "indequate" is corrected to read "inadequate".

30. On page 60477, in the first column, in paragraph (o)(2)(ii), lines 2 and 3 are corrected to read "e.g., it lacks any of the data required by this part, it presents"; in paragraph (o)(3), in the second line from the bottom, "paragraph (e)" is corrected to read "paragraph (g)".

§ 101.95 [Corrected]

31. On page 60477, the section heading for § 101.95 is corrected to read as follows:

§ 101.95 "Fresh," "freshly ," "fresh frozen," "frozen fresh".

Dated: February 21, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-4731 Filed 3-5-92; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 101

[Docket No. 91N-0099]

RIN 0905-AB67

Food Labeling: Health Claims; Dietary Fiber and Cardiovascular Disease; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a proposed rule that appeared in the **Federal Register** of November 27, 1991 (56 FR 60582). The document proposed not to authorize the use on foods, including dietary supplements, of health claims relating to the association between dietary fiber and cardiovascular disease. The document was published with some editorial errors. This document corrects those errors.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltzman, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0316.

In FR Doc. 91-27165, appearing on page 60582 in the **Federal Register** of Wednesday, November 27, 1991, the following corrections are made:

1. On page 60586, in the second column, in the first paragraph, in the third line from the bottom, "per 1,000 kcal" is corrected to read "g per 1,000 kcal"; and in the second paragraph, in the second line, "Implication" is corrected to read "Implications".

2. On page 60588, in the first column, in the second full paragraph, in the sixth line, "3 soluble" is corrected to read "3 g soluble"; and in the fourth full paragraph, in the seventh line, "(27" is corrected to read "(ages 27".

3. On page 60589, in the second column, in the third full paragraph, in the fourth line from the bottom, the word "was" is corrected to read "were".

4. On page 60590, in the first column, in the third full paragraph, in the third line, the word "isaqbol" is corrected to read "isagbol".

5. On page 60591, in the first column, in the second paragraph, in the fourth line, "Ref. 75" is corrected to read "Ref. 74"; in third paragraph, in the 17th line, "Ref. 74" is corrected to read "Ref. 73"; in the fourth paragraph, in the second line, "Ref. 73" is corrected to read "Ref. 72"; in the second column, in the second line, "Ref. 73" is corrected to read "Ref. 72"; and in the first full paragraph, in the eighth line from the bottom, "Ref. 72" is corrected to read "Ref. 51".

6. On page 60594, in the third column, in Reference 38, "Stamler, J.," should appear after "38." and "Population Studies in" should appear before the word "Nutrition".

7. On page 60595, in the third column, Reference 72 is removed and References 73, 74, and 75 are correctly redesignated as References 72, 73, 74, respectively.

Dated: February 21, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-4732 Filed 3-5-92; 8:45 am]

BILLING CODE 4160-01-M

federal register

Friday
March 6, 1992

Part III

Department of Health and Human Services

Health Care and Financing Administration

42 CFR Parts 417, et al.
Medicare and Medicaid Programs;
Advance Directives; Interim Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 417, 431, 434, 483, 484, 489 and 498

[BPD-718-IFC]

RIN 0938-AF50

Medicare and Medicaid Programs; Advance Directives

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule amends the Medicare and Medicaid regulations governing provider agreements and contracts to establish requirements for States, hospitals, nursing facilities, skilled nursing facilities, providers of home health care or personal care services, hospice programs and prepaid health plans concerning advance directives. An advance directive is a written instruction, such as a living will or durable power of attorney for health care, recognized under State law, relating to the provision of health care when an individual's condition makes him or her unable to express his or her wishes. The intent of these provisions is to enhance an individual's control over medical treatment decisions.

This rule implements sections 4206 and 4751 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101-508.

DATES: *Effective date:* This interim final rule is effective on April 6, 1992. However, statutory requirements at sections 1819(c)(1)(E), 1833(r), 1866(a)(1)(Q), 1876(c)(8), and 1891(a)(6) of the Social Security Act (the Act) have an effective date of December 1, 1991, and are effective on that date regardless of the effective date of this interim final rule.

Comment date: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on May 5, 1992.

ADDRESSES: Mail comments to the following address:

Health Care Financing Administration,
Department of Health and Human Services,
Attention: BPD-718-IFC,
P.O. Box 26676,
Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201; or
Room 132, East High Rise Building,
6325 Security Boulevard,
Baltimore, Maryland 21207.

Due to staffing and resource limitations, we cannot accept audio, video or facsimile (FAX) copies of comments. In commenting, please refer to file code BPD-718-IFC. Written comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202-245-7890).

Organizations and individuals desiring to submit comments on the reporting requirements discussed under the section on "Collection of Information Requirements" of this preamble should direct them to the Health Care Financing Administration at one of the addresses cited above, and to the Office of Information and Regulatory Affairs, Attention: Laura Oliven, Office of Management and Budget, New Budget, New Executive Office Building (Room 3002), Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Thomas Hoyer, (301) 966-4607.

SUPPLEMENTARY INFORMATION:

I. Background

Advances in medical treatment that permit life to be prolonged through the use of progressive medical equipment have raised complex legal and ethical issues relating to the rights of patients in making decisions as to whether such treatments should be used or, if used, should be continued. The issues raised generally fall within two categories: (1) What is the range of choices available to a patient with respect to treatment modalities; and (2) How can these choices be exercised, for example, in advance by means of a directive prepared by the individual before the need for treatment arises, or by another person on the individual's behalf when the individual no longer can make such determinations.

Because of the rising concern surrounding these issues, more and more attention is being focused on increasing the individual's control over his or her decisions concerning medical treatment through the use of advance directives.

Advance directives are written instructions recognized under State law relating to the provision of health care when individuals are unable to communicate their wishes regarding medical treatment. The advance directive may be a written document authorizing an agent or surrogate to make decisions on an individual's behalf (a durable power of attorney for health care), a written statement (a living will), or some other form of instruction recognized under State law specifically addressing the provisions of health care. The various legal devices that exist serve to enhance the ability of individuals to have their desires carried out in the event that they become unable to make their own medical treatment decisions.

Most States have enacted legislation defining a patient's rights to make decisions regarding medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. However, prior to the enactment of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101-508, there were no requirements relating to advance directives under Federal Medicare or Medicaid laws.

II. Legislative Amendments

A. Medicare Provisions

Section 1866 of the Act requires that providers of services under Medicare enter into an agreement (i.e., provider agreements) with the Secretary and comply with the requirements specified in that section. Section 4206(a) of OBRA '90 amended section 1866(a)(1) of the Act relating to Medicare provider agreements by adding a new subparagraph (Q), which specifies that to participate in the Medicare program, hospitals, skilled nursing facilities, home health agencies, and hospice programs must file an agreement with the Secretary to comply with the statutory requirements in new subsection 1866(f) of the Act concerning advance directives. Section 1866(f)(3) of the Act defines an advance directive as a written instruction, such as a living will or durable power of attorney for health care, recognized under State law, relating to the provision of health care when an individual is incapacitated. The State law may either be established by statute or as recognized by the courts of the State.

Section 1866(f)(1) of the Act specifies that a provider of services or prepaid or eligible organization (i.e., a health maintenace organization (HMO), competitive medical plan (CMP) as defined in section 1876(b) of the Act, or a health care prepayment plan (HCPP) as defined in section 1833(a)(1)(A) of the Act) must maintain written policies and procedures on advance directives with

respect to all adult individuals receiving medical care through the provider or organization. The provider or organization must provide written information to each individual concerning an individual's rights under State law to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. The provider or organization must also furnish each individual with the written policies of the provider or organization with respect to the implementation of advance directives.

Section 1866(f)(2) of the Act requires that this written information must be provided at the time an individual is admitted as an inpatient to a hospital, at the time of admission to a skilled nursing facility, before an individual comes under the care of a home health agency, at the time of initial receipt of hospice care, or at the time of enrollment of the individual with an eligible prepaid health care organization or HCPP.

Section 1866(f)(1) of the Act contains provisions that require the provider or organization to document in the individual's medical record whether or not the individual has executed an advance directive, not to discriminate against individuals based on whether or not they have executed an advance directive, to ensure compliance with State law, and to provide for education of staff and community on issues concerning advance directives.

Section 4206(b) of OBRA '90 amended section 1876(c) of the Act by adding a new paragraph (8), which provides that the contract between the Secretary and an eligible organization must provide that the organization meets the advance directives requirements specified in section 1866(f) of the Act.

Section 4206(b) of OBRA '90 also amended section 1833 of the Act by adding a new subsection (r), which specifies that the Secretary may not provide for payment under the Medicare program to an organization unless the organization provides assurances satisfactory to the Secretary that the organization meets the requirements relating to the maintenance of written policies and procedures regarding advance directives in section 1866(f) of the Act.

Section 4206(c) of OBRA '90 provides that sections 4206 (a) and (b) do not prohibit the application of a State law that allows for an objection on the basis of conscience for any health care provider or any agent of such provider which, as a matter of conscience, cannot implement an advance directive. If this is the case, we are requiring that the provider include a clear and precise explanation of this conscientious objection in its written policies and procedures that must be furnished to all adult individuals.

Section 4206(d) makes conforming amendments to sections 1819(c)(1) and 1891(a) of the Act, requiring that skilled nursing facilities and home health agencies, respectively, comply with the advance directives requirements in section 1866(f) of the Act. Enforcement procedures are explained in section D of this preamble.

B. Medicaid Provisions

Section 1902 of the Act sets forth State plan requirements for medical assistance that must be submitted to the Secretary for approval. Section 4751 of OBRA '90 amended section 1902 of the Act relating to requirements for State plans by adding provisions concerning advance directives comparable to the Medicare provisions in section 4206 of OBRA '90. Specifically, section 4751 of OBRA '90 amended section 1902 of the Act by adding new paragraph (57) to subsection (a) and a new subsection (w), which requires all hospitals, nursing facilities, providers of home health care and personal care services, hospices, or health maintenance organizations (as defined in section 1903(m)(1)(A) of the Act) that are receiving funds under a State plan to maintain written policies and procedures to inform, educate, and distribute written information on advance directives to all adult individuals receiving medical care by or through the provider or organization, in the manner described in the law.

Section 4751 also amended section 1902 of the Act by adding paragraph (58) to subsection (a) which requires that the State, acting through a State agency, association, or other private non-profit entity, develop a written description of the State law concerning advance directives to be distributed to Medicaid providers and health maintenance organizations.

Section 4751(b) makes conforming amendments to sections 1903(m)(1)(A) and 1919(c)(2) of the Act. These requirements are to be enforced under applicable State plan provisions.

C. Public Information Requirements

Section 4751(d) of OBRA '90 imposes an additional requirement on the Secretary to conduct a public education campaign on advance directives. This requirement is being pursued separately by HCFA.

D. Enforcement Procedures

For hospitals and hospices, Medicare enforcement procedures will be conducted in the same way provider agreements are enforced. That is, the provider agreement obligates a provider to comply with the applicable requirements of title XVIII and includes specific provisions. The Secretary may refuse to enter into a provider agreement or may refuse to renew or may terminate an agreement after the Secretary: (1) Determines that the provider fails to comply substantially with the provisions of the agreement or with the provisions of title XVIII and the implementing regulations; (2) Determines that the provider fails substantially to meet the applicable provisions of section 1861 of the Act (definition of services, institutions, etc.,); or (3) Has excluded the provider from participation under sections 1128 or 1128A of the Act (exclusion and civil monetary penalty provisions).

On-site surveys of providers are performed by State agency or Federal surveyors (generally on an annual basis) to determine compliance with the requirements or conditions of participation. However, providers are assumed to be in compliance with the other requirements of the provider agreement. HCFA does not routinely seek information to confirm that the provider is complying with the other requirements of the provider agreement. If information concerning a provider's compliance with the agreement of the provisions of title XVIII is needed, it may be obtained in several ways, including the performance of an on-site survey.

Each hospital and hospice provider will be informed of its obligation to comply with the advance directive provisions and that these provisions are required as a part of its provider agreement with HCFA. Compliance with these provisions is necessary for continued participation in the Medicare and Medicaid programs. These providers will be required to inform HCFA, in writing, of the date they achieve compliance. For hospices, and hospitals not accredited by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) and/or the American Osteopathic Association (AOA), compliance will be verified as part of the routine survey process.

Periodic Federal recertification surveys are not conducted in hospitals that are accredited by the Joint Commission and/or AOA because such hospitals are "deemed" to meet

Medicare's certification requirements. However, since accredited hospitals are not "deemed" to meet the utilization review requirements and the advance directive requirements, we do investigate complaints and conduct sample validation surveys at these hospitals. We will verify compliance with the advance directive provisions at accredited hospitals in response to complaints and at the time of these sample validation surveys.

For skilled nursing facilities and home health agencies, enforcement procedures will employ the Federal on-site survey process. State agency or Federal surveyors are responsible for evaluating compliance with the Medicare requirements or conditions of participation. These surveys are generally conducted on an annual basis. Therefore, State agency or Federal surveyors would be able to evaluate on-site compliance with the advance directive requirements through the use of the survey protocol for skilled nursing facilities and home health agencies.

A facility found out of compliance with the provider agreement may be terminated by HCFA. HCFA must give the provider notice of termination at least 15 days before the effective date of termination of the provider agreement. This notice must state the reasons for, and effective date of termination and explain the extent to which services may continue after that date. A provider may appeal the termination of its provider agreement in accordance with part 498.

Under Medicaid, a provider must enter into an agreement with the State Medicaid agency. State agency surveyors or Federal surveyors (during a validation or "look-behind" survey) perform a function similar to that under Medicare. However, the State Medicaid agency is responsible for assuring compliance with the Medicaid provider agreement and the advance directive requirements contained therein.

For eligible organizations, this provision will be enforced as a contract requirement. Organizations must comply with the advance directives requirements in order to receive a contract. Failure to continue compliance with these requirements, as determined by HCFA during routine monitoring reviews, may result in termination of the contract.

Health care prepayment plans also must comply with the advance directives requirements and must provide us with satisfactory assurances that they are in compliance with these requirements in order to receive payment. Failure to continue compliance with these requirements, as determined by HCFA during routine monitoring reviews, may result in termination of a health care prepayment plan's agreement with HCFA.

E. Effective Dates

The amendments made by sections 4206 (a) and (d) of OBRA '90 pertaining to Medicare providers are effective with respect to services furnished on or after December 1, 1991.

The amendments made by section 4206(b) of OBRA '90 pertaining to prepaid and eligible organizations participating in the Medicare program (i.e., contracts with HMOs and CMPs under section 1876(b), and Medicare payments to organizations under section 1833(a)(1)(A) of the Act) are effective December 1, 1991.

The amendments made by section 4751 of OBRA '90 pertaining to the Medicaid program are effective with respect to services furnished on or after December 1, 1991.

III. Provisions of the Proposed Regulations

To implement the provisions of sections 4206 and 4751 of OBRA '90, we are requiring that all hospitals, skilled nursing facilities, nursing facilities, providers of home health care or personal care services, hospices, and prepaid health plans provide written information to each adult individual receiving medical care through the provider or organization concerning his or her rights under State law to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. Under these regulations, the term "advance directive" is defined as a written instruction, such as a living will or durable power of attorney for health care, recognized under State law, relating to the provision of health care when the individual is incapacitated. These regulations do not require an individual to execute an advance directive prior to the provision of treatment and services. Furthermore, we note that these requirements do not apply to providers of outpatient hospital services.

The provider or organization must inform the individual, in writing, of State laws regarding advance directives; inform the individual, in writing, of the policies of the provider or organization regarding the implementation of advance directives, including a clear and precise explanation of a conscientious objection for any health care provider or any agent of such provider which, as a matter of conscience, cannot implement an advance directive; document in the individual's medical record whether or not the individual has executed an advance directive; educate staff on issues concerning advance directives; and provide for community education regarding advance directives.

Nothing in either the statute or this interim final rule addresses patient or provider rights or obligations concerning either notification or decisions regarding medical or non-medical care, except when the patient has left written instructions which become effective only after the individual becomes incapacitated. For example, this regulation neither creates nor affects requirements with respect to informed consent to medical care, determination of mental capacity, provision of medical care to minors, wills leaving property, or organ donation. These and many other significant subjects are not addressed under OBRA '90. The law has a narrow and explicit focus solely of the handling of written directives for medical care made by persons who later become incapacitated.

We do not intend, in these regulations, to prescribe the content and format of the written information to be provided to each adult individual. However, in connection with our technical assistance responsibilities to States in meeting the Medicaid requirements of the law, HCFA's Administrator sent a letter to each State Medicaid Director to which was attached a sample public information document for use in informing adult individuals about advance directives. This sample public information document is suggestive of what we believe an acceptable document should include. Providers choosing to use this sample should include information regarding an individual's rights under State law to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, an advance directive.

Alternatively, it would be consistent with the statute to develop considerably shorter discussion than that contained in the sample document. It would also be possible to use a short summary notice, several paragraphs rather than pages long, which notified the patient that a longer and more specific document was available upon request. However, the summary notice would have to cover the legally-required elements (e.g. describe the purpose and the concept of an advance directive, describe State law, and describe the provider's policy and procedures).

The material contained in the HCFA Administrator's information package, including the sample public information document, may be found in Appendix I of this preamble.

We are aware that State law on this issue is not always clear. For example, some States may have no statute regarding advance directives, or State law may be a matter of common law or institutional practice rather than a State statute. Additionally, pending litigation may affect the status of existing statutes or legal precedents in other States. A State statute may also be silent on a particular issue, such as whether a provider may decline to follow a directive to which it conscientiously objects. Such silence may not necessarily mean that the omitted action is prohibited. Providers should be careful not to reach such a conclusion absent authoritative interpretation of a particular State's written and unwritten law.

Nonetheless, Congress has mandated that, as of December 1, 1991, providers and organizations participating in Medicare and Medicaid must distribute the required materials that inform an individual of his or her right under State law to accept or refuse medical treatment. Providers and organizations should be aware that this requirement relates to current State law. Therefore, changes in State law, by statute or court case, must be incorporated into subsequent provider information packages. We specifically seek public comments on what would be a reasonable period of time within which such changes should be made.

Written information on advance directives must be provided to an individual upon each admission to a medical facility and each time an individual comes under the care of a home health agency or hospice. For example, if a person is admitted first as an inpatient to a hospital and then to a nursing home, both the hospital and the nursing home would be required to provide information on advance directives to the individual. If an individual is being transferred from a hospital to a nursing home, the hospital discharge planner may provide the information (including the nursing home's policies regarding the implementation of advance directives) on behalf of the nursing home in the course of coordinating the smooth transfer of the patient. However, the nursing home will still be responsible for documenting in the individual's medical record whether or not the individual has executed an advance directive.

If a patient is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, then the facility should give advance directive information to the patient's family or surrogate to the extent that it issues other materials about policies and procedures to the family of the incapacitated patient or to a surrogate or other concerned persons in accordance with State law. This does not, however, relieve the facility of its obligation to provide this information to the patient once he or she is no longer incapacitated or unable to receive such information.

As a part of the Medicaid requirements contained in section 4751 of OBRA '90, we are requiring in these regulations that each State, acting through a State agency, association, or other private nonprofit entity, develop a written description of the State law (i.e., statutory or otherwise recognized in the courts) concerning advance directives to be distributed by providers or organizations under the requirements of this section. Given the requirements in the Federal law, States have a wide range of options in describing State law and in prescribing informational materials for use by providers and organizations. For example, the State materials describing an individual's rights to accept or refuse medical treatment and the right to formulate an advance directive could include lengthy or extended requirements for executing an advance directive, or they could be a short, simple statement expressing the individual's rights concerning advance directives.

The following discussion reflects some possible approaches that States, providers, and organizations may choose to take in providing the required information and which we believe would produce results consistent with the statutory requirements. In accordance with the requirements of section 4751 of OBRA '90, States could require that Medicaid providers use the State-developed description of State law only. Alternatively, States could allow providers to incorporate the general information contained in the State-developed description of State law into the providers' own package of materials that include the providers' written policies regarding the implementation of an individual's rights. Although the statute does not specifically require that Medicare providers use the State-developed description of State law, we encourage States, providers, and organizations to work together to ensure that a complete and accurate description of State law is distributed consistently to all adult patients or residents.

As mentioned earlier, HCFA has provided technical assistance to the States, including the technical assistance information package released by HCFA's Administrator in September. Also in September, HCFA released a State Medicaid Manual issuance (HCFA-Pub. 45-2, Transmittal #73) concerning advance directive requirements to inform the States of their responsibilities in this area. Copies can be obtained by the general public by contacting the National Technical Information Service (NTIS), ORDER #PB88-952399. You may call to order at (703) 487-4630 or send a request to NTIS Subscription Department, 5285 Port Royal Road, Springfield, VA 22161.

Finally, we note that a number of other private entities have prepared pertinent documents that States may find helpful. HCFA's Administrator issued a press package that included a bibliography of these publications, as well as a list of organizations that have addressed the statutory requirement that providers disseminate information to adult individuals regarding their rights under State law to accept or refuse medical treatment and the right to formulate advance directives. These materials may be found at appendix II of this preamble.

The law requires that the existence of an advance directive be documented in an individual's medical record. We recognize, particularly in the case of prepaid health care organizations, that such documentation will occur when the medical record is created. Although the statute does not specifically require providers or organizations to have direct dialogue with each adult individual to ascertain whether he or she has executed an advance directive, we believe that this type of interaction is an acceptable method for obtaining this information.

Although it is acceptable that the patient be asked and respond to a specific question, we recognize that these procedures are not the only appropriate methods for obtaining the information needed to document medical records. Alternatives, such as community education campaigns, also may prove acceptable for obtaining this information. It is also acceptable for providers to include in preadmission materials a form, to be completed by the patient, that sets forth whether or not the patient has executed an advance directive. Such form, when completed and returned by the patient at the time of admission, would supply the provider the information needed to document the

medical record, or the form itself could be attached to such record. There are, however, issues with respect to whether these methods may impose too great a burden on the patient or may not result in eliciting the desired information from a sufficient number of patients. Therefore, we request comments on these and other methods of obtaining the information needed to document the medical record.

Concerning the requirement that a provider or organization provide for community education, there are several options available in order to accomplish this. For example, the provider or organization may use its community relations office as its vehicle to educate the community by incorporating the provisions of provider information and applicable State laws on advance directives in its existing publications. Alternatively, providers may simply opt to distribute to the community the same pamphlet developed specifically for its adult patients. The educational materials must inform the public of their rights under State law to make decisions concerning the receipt of medical care by or through the provider or organization; the right to formulate advance directives; and the provider or organization's implementation policies concerning advance directives. Whatever method is used, it must be in writing and subject to survey review for compliance with Federal requirements.

Under these regulations, the provider or organization cannot condition the provision of care or discriminate against an individual based on whether or not the individual has executed an advance directive. For example, all patients are generally entitled to the medically necessary care ordered by a physician which a provider, under normal procedures, would be required to furnish, and the care cannot be delayed or withheld because the individual has not executed an advance directive or the provider is waiting for an advance directive to be executed. However, once it is documented that an advance directive has been executed, then the directive takes precedence over the provision of the facility's normal procedures, to the extent required by State law.

As specified in the statute, we are requiring prepaid health care organizations to provide information on advance directives to enrollees at the time of enrollment. Organizations must give enrollees the advance directive material prior to the effective date of coverage. However, we encourage organizations to give enrollees the material as early as possible after the application for enrollment is received. We are clarifying this issue to avoid misunderstanding and confusion about the time when prepaid health care organizations must provide the required written information regarding advance directives to an adult individual.

We recognize that a prepaid health care organization may have contracts with a variety of providers (in order to assure widespread access to care), and that some of these providers may have policies with respect to advance directives that are more limited than others (e.g., a hospital exercising a reservation of conscience consistent with State law). In such cases, the prepaid health care organization could adopt a policy that embraces the variety of practices of its providers, and disseminate the information regarding those various practices to its enrollees as prescribed by this interim final rule. This information would be provided along with the written description of State law. On the other hand, the prepaid health care organization could simply note, in the material regarding State law and provider practices, that its providers have, in accordance with State law, varying practices regarding the implementation of an individual's advance directive. In this case, such varying practices must be made available to each adult individual selecting or receiving care from such providers.

Specifically, this regulation—

- Changes the title of part 489 to Provider and Supplier Agreements and adds a new subpart I to part 489 to include the requirements of section 1866(f) of the Act for Medicare and Medicaid providers pertaining to advance directives.
- Adds a new paragraph (d) to § 417.436, Membership rules for enrollees, to include the requirements of section 1866(f) of the Act for prepaid health care organizations, and cross-references these requirements in § 417.801, which specifies requirements for agreements between HCFA and health care prepayment plans.
- Adds a new § 431.20 to specify States' responsibility for developing a written description of the State law concerning advance directives to be distributed by providers and organizations under the requirements of part 489, subpart I and § 417.428(b).
- Cross-references the requirements in part 489, subpart I in § 417.472, which specifies the basic Medicare contract requirements; § 431.107, which specifies requirements for Medicaid provider agreements; § 483.10, which specifies resident rights as a requirement for long-term care facilities; § 484.10, which specifies patient rights as a condition of participation for home health agencies; and § 489.10, which specifies the basic requirements for Medicare provider agreements.
- Adds a new § 434.28 to subpart C of 42 CFR part 434, Contracts with HMOs and PHPs: Contract Requirements, to specify that a risk comprehensive contract with an HMO must comply with the requirements in part 489, subpart I.
- Adds a new paragraph (11) to § 498.3, which includes advance directives in the initial determinations that HCFA makes for appeals that affect participation in the Medicare program.

IV. Waiver of Notice of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking for a regulation to provide a period for public comment. However, we may waive that procedure if we find good cause that prior notice and comment are impractical, unnecessary, or contrary to public interest. In addition, section 4207(j) of OBRA '90 gives the Secretary authority to issue interim final regulations to implement the provisions of OBRA '90 as he deems necessary.

In order to establish our rules as quickly as possible to allow the provider community the greatest lead time to undertake this activity, and because of the statutory effective date for implementation of these provisions, we are asserting our privilege under section 4207(j) of OBRA '90 to issue these regulations as interim final rules with comment period. We are providing a 60-day comment period for public comment on the rules, and will respond to issues raised by commenters in any subsequent final rules.

V. Regulatory Impact Statement

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any final rule that meets one of the E.O. 12291 criteria for a "major rule"; that is, that would be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we do not consider States or individuals to be small entities.

These interim final rules amend the Medicare and Medicaid regulations governing priovider agreements and contracts by implementing certain changes made by OBRA '90. The changes establish requirements for States, hospitals, nursing facilities, skilled nursing facilities, providers of home health care or personal care services, hospice programs and prepaid health plans concerning advance directives.

Based on the discussions presented in this preamble, we have concluded that performing the functions necessary to meet the minimal requirements of this interim final rule, as required by the statute, would not cause a consequential expenditure of time and effort. Therefore, we have concluded that this is not a major rule and have not prepared a final regulatory impact statement under E.O. 12291 or a regulatory flexibility analysis under the RFA.

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final rule will have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that has fewer than 50 beds and is located outside a Metropolitan Statistical Area.

We have determined, and the Secretary certifies, that these interim final rules with comment period will not have a significant economic impact on the operations of a substantial number of small rural hospitals, and therefore have not prepared a rural hospital impact statement.

VI. Collection of Information Requirements

Sections 417.436(d)(iii), 489.102(a)(2), 417.801(b)(5), 431.107(b)(4), 434.28, 483.10(b)(8), and 484.10(c)(2)(ii) of this interim final rule contain information collection requirements that are subject to the Office of Management and Budget review under the Paperwork Reduction Act of 1980. These information collections require hospitals, nursing facilities, skilled nursing facilities, providers of home health care or personal care services, hospice programs and prepaid health plans to document in the medical record whether or not an advance directive. We estimate the collection burden for each provider or organization employee to be approximately three minutes per medical record. We estimate an overall total of 32,800 providers and organizations (approximately 6,740 hospitals; 990 hospices; 15,830 SNFs/NFs; 5,830 home health agencies; 3,100 personal care providers; and 310 prepaid health plans) to be affected by these information collections. We project that for fiscal year 1992, approximately 15 million individuals will use the services of these providers and organizations. Therefore, we estimate the overall collection burden to be 750,000 hours (15 million individuals × 3 minutes/record = 750,000 hours).

Section 431.20(b) requires States to submit State plan preprint amendments that contain a written description of its law(s) concerning advance directives. We estimate the information collection burden for the 50 States and 4 U.S. territories to be approximately 3 hours per amendment, with an overall burden of 162 hours (54 States and territories × 3 hours/amendment = 162 hours).

There are no reporting requirements associated with these information collections. A notice will be published in the **Federal Register** when approval is obtained. Other organizations and individuals desiring to submit comments regarding the estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should address their comments to the OMB official whose name appears in the "ADDRESSES" section of this preamble.

VII. Response to Public Comments

Because of the large volume of public comments that we usually receive on rules, we cannot acknowledge or respond to them individually. However, we will address all public comments received on this document by the date and time specified in the "DATES" section of this preamble in any subsequent final regulations.

Appendix I to the Preamble

September 5, 1991.

Under provisions of the Omnibus Budget Reconciliation Act of 1990, States are responsible for developing written descriptions of State law regarding an adult individual's right to make decisions concerning medical care. This includes the right to formulate advance directives, such as a living will or a durable power of attorney for health care.

A State, acting through a State agency, association, or other private, nonprofit entity, is required to develop a written description of the State law concerning advance directives. Beginning December 1, 1991, Medicare- and Medicaid-certified hospitals, nursing facilities, and other affected providers and organizations must give adults information on advance directives (see summary of the Federal statute enclosed).

Many States have already convened meetings between provider and consumer representatives and State officials to discuss ways in which to clearly and succinctly write a description of State law on advance directives. Some States already have drafts of those statements completed.

I would like to offer assistance to those States that have not begun the drafting process or that would like some technical assistance in this process. Enclosed is a paper on advance directives that will be part of our public education materials that the Health Care Financing Administration (HCFA) in coordination with the Social Security Administration and the Administration on Aging, will distribute to national news media and consumer publications, and through State and local area Agencies on Aging.

The paper answers basic questions about advance directives and raises the issue in a balanced way that makes clear several points. First, the law does *not* require an individual to execute an advance directive. Second, people can use advance directives to say "yes" to treatment that they want or to say "no" to any treatment that they do not want.

As your State develops its written description on advance directives, I hope that you keep in mind the need for individuals not only to be given basic definitions of terms used, but also to understand the range of options available to them, if they decide to execute an advance directive.

HCFA will also soon send you State Medicaid Manual instructions that will provide you guidelines in implementing the advance directive statutory provisions. If you need additional assistance on this important project in the coming weeks, please contact your HCFA Regional Administrator.

Sincerely,

Gail R. Wilensky,

Administrator.

Enclosures.

(Sample Public Information Document)

Advance Directives—The Patient's Right to Decide

All adult individuals in hospitals, nursing homes, and other health care settings have certain rights. For example, you have a right to confidentiality of your personal and medical records and to know what treatment you will receive.

You also have another right. You have the right to fill out a paper, known as an "advance directive." The paper says in advance what kind of treatment you want or do not want under special, serious medical conditions—conditions that would prevent you from telling your doctor how you want to be treated. For example, if you were taken to a hospital in a coma, would you want the

hospital's medical staff to know your specific wishes about decisions affecting your treatment?

This article answers some questions related to a new federal law taking effect December 1, 1991 that requires most hospitals, nursing facilities, hospices, home health care programs and health maintenance organizations (HMOs) to give you information about advance directives and your legal choices in making decisions about medical care. The law is intended to increase your control over medical treatment decisions.

The information in this article can help you make decisions in advance of treatment. Because this is an important matter, however, you may wish to talk to family, close friends, and your doctor *before* deciding whether you want an advance directive.

Finally, it is important to remember that state laws differ about the legal choices available to individuals for treatment options that can be honored by hospitals and other health care providers and organizations. Beginning December 1, 1991 these health care professionals should have information for you on your state's advance directive law.

What Is an Advance Directive?

Generally, an advance directive is a written statement, which you complete in advance of serious illness, about how you want medical decisions made. The two most common forms of advance directive are:

- a "Living Will"; and
- a "Durable Power of Attorney for Health Care."

An advance directive allows you to state your choices for health care or to name someone to make those choices for you, if you become unable to make decisions about your medical treatment. In short, an advance directive can enable you to make decisions about your future medical treatment. You can say "yes" to treatment you want, or say "no" to treatment you don't want.

What Is a Living Will?

A Living Will generally states the kind of medical care you want (or do not want) if you become unable to make your own decision. It is called a "living will" because it takes effect while you are still living.

Most states have their own living will forms, each somewhat different. It may also be possible to complete and sign a pre-printed living will form available in your own community, draw up your own form, or simply write a statement of your preferences for treatment. You may also wish to speak to an attorney or your physician to be certain you have completed the living will in a way that your wishes will be understood and followed.

What Is a Durable Power of Attorney for Health Care?

In many states, a "Durable Power of Attorney for Health Care" is a signed, dated, and witnessed paper naming another person, such as a husband, wife, daughter, son, or close friend, as your "agent" or "proxy" to make medical decisions for you if you should become unable to make them for yourself. You can include instructions about any treatment you want or wish to avoid. Some states have specific laws allowing a health care power of attorney and provide printed forms.

Which Is Better: A Living Will or a Durable Power of Attorney for Health Care?

In some states, laws may make it better to have one or the other. It may also be possible to have both, or to combine them in a single document that describes treatment choices in a variety of situations (ask your doctor about these) and name someone (called your "agent" or "proxy") to make decisions for you, should you be unable to make decisions for yourself.

Do I Have to Write an Advance Directive Under the New Law?

No. It is entirely up to you.

Can I Change My Mind After I Write a Living Will or Health Care Power of Attorney?

Yes. You may change or cancel these documents at any time in accordance with state law. Any change or cancellation should be written, signed, and dated in accordance with state law, and copies should be given to your doctor, or to others to whom you may have given copies of the original. In addition, some states allow you to change an advance directive by oral statement.

If you wish to cancel an advance directive while you are in the hospital, you should notify your doctor, your family, and others who may need to know.

Even without a change in writing, your wishes stated in person directly to your doctor generally carry more weight than a living will or durable power of attorney, as long as you can decide for yourself and can communicate your wishes. But be sure to state your wishes clearly and be sure that they are understood.

What if I Fill Out an Advance Directive in One State and am Hospitalized in a Different State?

The law on honoring an advance directive from another state is unclear. Because an advance directive tells your wishes regarding medical care, however, it may be honored wherever you are, if it is made known. But if you spend a great deal of time in more than one state, you may wish to consider having your advance directive meet the laws of both states, as much as possible.

What Should I Do With My Advance Directive if I Choose to Have One?

Make sure that someone, such as your lawyer or family member, knows that you have an advance directive and knows where it is located. You might also consider the following:

- If you have a durable power of attorney, give a copy or the original to your "agent" or "proxy."
- Ask your physician to make your advance directive part of your permanent medical record.
- Keep a second copy of your advance directive in a safe place where it can be found easily, if it is needed.
- Keep a small card in your purse or wallet, which states that you have an advance directive and where it is located and who your "agent" or "proxy" is, if you have named one.

Under the new law, when you enter a Medicare or Medicaid hospital or nursing facility, receive home health or hospice care from a Medicare or Medicaid provider, or enroll in a Medicare or Medicaid certified HMO, you should be asked whether you have an advance directive.

For further information, please ask those who are in charge of your care.

Appendix II to the Preamble

National Resources on Advance Directives

The following list of organizations and publications does not reflect an endorsement of the organizations or publications by the Department of Health and Human Services or the Health Care Financing Administration, nor are these materials intended to encourage or discourage any particular action by an individual concerning advance directives.

The following list is a sampling of organizations and publications that have more information on the issue of advance directives. The organizations listed were those that contacted the Health Care Financing Administration regarding the Agency's implementation of the advance directives statute and that addressed the statutory requirement that providers disseminate information to adult individuals regarding their rights under state law to accept or refuse medical treatment and the right to formulate advance directives. The organizations provide a national and geographic sample of consumer, legal, and bioethics groups. The publications listed below were submitted unsolicited to the Health Care Financing Administration.

Organizations

The American Bar Association, Commission on Legal Problems of the Elderly, 1800 M Street, NW., Washington, DC 20036, 202/331-2297

American Health Decisions, 319 E. 46th Street, #9V, New York, NY 10017, 212/268-8900

Hastings Center, Institute of Society, Ethics, and the Life Sciences, 255 Elm Road, Briarcliff Manor, NY 10510, 914/478-0500

Pacific Center of Health Policy and Ethics, 444 Law Center, University of Southern California, Los Angeles, CA 90089, 213/740-2541

Publications

"The Patient Self-Determination Directory and Resource Guide," a directory of national and local organizations that have expertise in the area of autonomous health care decision making.

National Health Lawyers Association, Development Office, 1620 Eye Street, NW., Suite 900, Washington, DC 20006

"A Matter of Choice: Planning Ahead for Health Care Decisions," includes information about living wills, durable powers of attorney, and statutory regulations.

American Association of Retired Persons, Fulfillment Division, Publication Number D12778, 601 E. Street, NW., Washington, DC 20049

"The Complete Guide to Living Wills," a book that answers common questions about the content and function of living wills and other advance directives, and describes a step-by-step process for preparing an advance directive.

By Doron Weber, Bantam Books

"A Patient Guide to Advance Directives" and "A Physician Guide to Advance Directives," two brochures that explain living wills and durable powers of attorney and answer common questions about these and other advance directives.

Health Law Division, American Medical Association, 515 North State Street, 14th Floor, Chicago, IL 60610

"Making Health Decisions for Your Future: Advance Directives," a brochure that answers some commonly asked questions about advance directives.

Midwest Bioethics Center, 410 Archibald, Suite 106, Kansas City, MO 64111

"Advance Directives: Guaranteeing Your Health Care Rights," a 10-minute video with printed material on advance directives.

American Hospital Association Services, Inc., Catalogue Number 058-604, P.O. Box 92683, Chicago, IL 60675-2683

"Making Sense of Advance Directives," a book that presents a historical look at the patient's role in medical decision making, with special attention given to the problems of advance decision making.

By Nancy King, Kluwer Academic Publishers, 101 Philip Drive, Norwell, MA 02061

"Partners in Health Care," a 15-minute videotape dramatizing a "real life" situation in which family members come to grips with the need to discuss the issue of advance directives.

California Health Decisions, 505 S. Main Street, Suite 400, Orange, CA 92668

"Asking About Advance Directives: Scenarios for Healthcare Providers," a 20-minute videotape that presents three typical admissions scenarios and that stresses positive behaviors by medical staff in asking about whether a patient/resident has an advance directive.

The Catholic Health Association of the United States, 4455 Woodson Road, St. Louis, MO 63134-3797.

"Make Your Wishes Known," a series of videotapes and written materials—some of which have been translated into Spanish—about advance directives.

Life Management, P.O. Box 2170, Columbia, SC 29202

Note: This publication was not part of the bibliography that was included in the press package issued by HCFA's Administrator.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Health maintenance organization (HMO), Medicare, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 434

Grant programs—health, Health maintenance organizations (HMO), Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, health professions, Health records, Medicaid, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Administrative practice and procedure, Health facilities, Health professions, Home health agencies, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare.

42 CFR Part 498

Administrative practice and procedure, Appeals, Medicare practitioners, providers and suppliers.

TITLE 42—PUBLIC HEALTH

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Chapter IV of title 42 is amended as set forth below:

SUBCHAPTER B—MEDICARE PROGRAM

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

A. Part 417 is amended as follows:

1. The authority citation for part 417 is revised to read as follows:

Authority: Secs. 1102, 1833(a)(1)(A), 1861(s)(2)(H), 1866(a), 1871, 1874, and 1876 of the Social Security Act (42 U.S.C. 1302, 13951(a)(1)(A), 1395x(s)(2)(H), 1395cc(a), 1395hh, 1395kk, and 1395mm); sec. 114(c) of Pub. L. 97-248 (42 U.S.C. 1395mm note); 31 U.S.C. 9701; and secs. 215 and 1301 through 1318 of the Public Health Service Act (42 U.S.C. 216 and 300e through 300e-17), unless otherwise noted.

Subpart K—Enrollment, Entitlement, and Disenrollment Under Medicare Contract

2. In § 417.436, the introductory text in paragraph (a) is republished and the paragraph is amended by revising paragraph (5), redesignating paragraph (6) as paragraph (7) and revising it, and adding a new paragraph (6), and adding a new paragraph (d) to read as follows:

§ 417.436 Membership rules for enrollees.

(a) *Maintaining rules.* An organization must maintain written membership rules that deal with, but need not be limited to—

* * * * *

(5) How and where to obtain services from or through the organization;

(6) Advance directives as specified in paragraph (d) of this section; and

(7) Any other matters that HCFA may prescribe.

* * * * *

(d) *Advance directives.* (1) An organization must maintain written policies and procedures concerning advance directives, as defined in § 489.100 of this chapter, with respect to all adult individuals receiving medical care by or through the organization and are required to:

(i) Provide written information to such individuals concerning—

(A) An individual's rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives; and

(B) The written policies of the organization respecting the implementation of such rights, including a clear and precise statement of limitation if the organization cannot implement an advance directive as a matter of conscience;

(ii) Provide the information specified in paragraphs (d)(1)(i) of this section to each enrollee at the time of enrollment.

(iii) Document in the individual's medical record whether or not the individual has executed an advance directive;

(iv) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(v) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives;

(vi) Provide for education of staff concerning its policies and procedures on advance directives; and

(vii) Provide for community education regarding advance directives either directly or in concert with other providers or organizations.

(2) The organization—

(i) Is not required to provide care that conflicts with an advance directive.

(ii) Is not required to implement an advance directive if, as a matter of conscience, the provider cannot

implement an advance directive and State law allows any health care provider or any agency of such provider to conscientiously object.

Subpart L—Medicare Contract Requirements

3. In § 417.472, paragraph (f) is redesignated as paragraph (g) and a new paragraph (f) is added to read as follows:

§ 417.472 Basic contract requirements.

* * * * *

(f) *Requirements for Advance Directives.* The organization must meet all the requirements for advance directives at § 417.436(d) of this part.

* * * * *

Subpart U—Health Care Prepayment Plans

3. In § 417.801(b), the introductory material is republished and the paragraph is amended by revising paragraph (4), redesignating paragraph (5) as paragraph (6) and revising it and adding a new paragraph (5) to read as follows:

§ 417.801 Agreements between HCFA and health care prepayment plans.

* * * * *

(b) *Terms.* The agreement must provide that the HCPP agrees to—

* * * * *

(4) Not impose any limitations on the acceptance of Medicare enrollees or beneficiaries for care and treatment that it does not impose on all other individuals;

(5) Meet the advance directives requirements specified in § 417.436(d) of this part; and

(6) Consider any additional requirements that HCFA finds necessary or desirable for efficient and effective program administration.

* * * * *

SUBCHAPTER C—MEDICAL ASSISTANCE PROGRAMS

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

B. Part 431 is amended as follows:

1. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act. (42 U.S.C. 1302).

Subpart A—Single State Agency

2. In subpart A, a new § 431.20 is added, and the table of contents is revised accordingly, to read as follows:

§ 431.20 Advance directives.

(a) *Basis and purpose.* This section, based on section 1902(a) (57) and (58) of the Act, prescribes State plan requirements for the development and distribution of a written description of State law concerning advance directives.

(b) A State Plan must provide that the State, acting through a State agency, association, or other private nonprofit entity, develop a written description of the State law (whether statutory or as recognized by the courts of the State) concerning advance directives, as defined in § 489.100 of this chapter, to be distributed by Medicaid providers and health maintenance organizations (as specified in section 1903(m)(1)(A) of the Act) in accordance with the requirements under part 489, subpart I of this chapter.

Subpart C—Administrative Requirements: Provider Relations

3. In subpart C, § 431.107 is amended by revising paragraph (a), republishing the introductory material in paragraph (b), revising paragraphs (b)(2) and (b)(3), and adding a new paragraph (b)(4) to read as follows:

§ 431.107 Required provider agreement.

(a) *Basis and purpose.* This section sets forth State plan requirements, based on sections 1902(a)(4), 1902(a)(27), 1902(a)(57), and 1902(a)(58) of the Act, that relate to the keeping of records and the furnishing of information by all providers of services (including individual practitioners and groups of practitioners).

(b) *Agreements.* A State plan must provide for an agreement between the Medicaid agency and each provider or organization furnishing services under the plan in which the provider or organization agrees to:

* * * * *

(2) On request, furnish to the Medicaid agency, the Secretary, or the State Medicaid fraud control unit (if such a unit has been approved by the Secretary under § 455.300 of this chapter), any information maintained under paragraph (b)(1) of this section and any information regarding payments claimed by the provider for furnishing services under the plan;

(3) Comply with the disclosure requirements specified in part 455, subpart B of this chapter; and

(4) Comply with the advance directives requirements for hospitals, nursing facilities, providers of home health care and personal care services, hospices, and HMOs specified in part 489, subpart I, and § 417.436(d) of this chapter.

PART 434—CONTRACTS

C. Part 434 is amended as follows:

1. The authority citation for part 434 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart C—Contracts With HMOs and PHPs: Contract Requirements

2. In subpart C, a new § 434.28 is added to read as follows:

3. A new § 434.28 is added to read as follows:

§ 434.28 Advance directives.

A risk comprehensive contract with an HMO must provide for compliance with the requirements of subpart I of part 489 of this chapter relating to maintaining written policies and procedures respecting advance directives. This requirement includes provisions to inform and distribute written information to adult individuals concerning policies on advance directives, including a description of applicable State law.

SUBCHAPTER E—STANDARDS AND CERTIFICATION

PART 483—REQUIREMENTS FOR LONG TERM CARE FACILITIES

D. Part 483 is amended as follows:

1. The authority citation for part 483 is revised to read as follows:

Authority: Sec. 1102, 1819 (a)–(d), 1861 (j) and (l), 1863, 1866(a), 1871, 1902(a)(28), 1905 (a) and (c), and 1919(a)–(d) of the Social Security Act (U.S.C. 1302, 1395(i)(3) (a)–(d), 1395x (j) and (l), 1395z, 1395cc(a), 1395hh, 1396a(a)(28), 1396d (a) and (c) and 1396r (a)–(d)), unless otherwise noted.

Subpart B—Requirements for Long Term Care Facilities

2. In § 483.10, the introductory text is republished and paragraph (b) is amended by revising paragraph (4), redesignating existing paragraphs (8) through (10) as paragraphs (9) through (11) and revising them, and by adding a new paragraph (8) to read as follows:

§ 483.10 Resident rights.

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights:

* * * * *

(b) *Notice of rights and services.*

* * * * *

(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section; and

* * * * *

(8) The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law.

(9) The facility must inform each resident of the name, specialty, and way of contacting the physician responsible for his or her care.

(10) The facility must prominently display in the facility written information, and provide to residents and applicants for admission oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

(11) *Notification of changes.* (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal respresentative or an interested family member when there is—

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility as specified in § 483.12(a).

(ii) The facility must also promptly notify the resident and, if known, the resident's legal representative or interested family member when there is—

(A) A change in room or roommate assignment as specified in § 483.15(e)(2); or

(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (b)(1) of this section.

(iii) The facility must record and periodically update the address and phone number of the resident's legal representative or interested family member.

* * * * *

PART 484—CONDITIONS OF PARTICIPATION: HOME HEALTH AGENCIES

E. Part 484 is amended as follows:

1. The authority citation for Part 484 is revised to read as follows:

Authority: Sec. 1102, 1861, 1866(a), 1871 and 1891 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395cc(a), 1395hh, and 1395bbb).

Subpart B—Administration

2. In § 484.10, the introductory text is republished and paragraph (c)(2) is revised to read as follows:

§ 484.10 Condition of participation: Patient rights.

The patient has the right to be informed of his or her rights. The HHA must protect and promote the exercise of these rights.

* * * * *

(c) *Standard: Right to be informed and to participate in planning care and treatment.*

* * * * *

(2) The patient has the right to participate in the planning of the care.

(i) The HHA must advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

(ii) The HHA complies with the requirements of subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law.

* * * * *

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

F. Part 489 is amended as follows:

1. The title of part 489 is revised to read as follows:

PART 489—PROVIDER AND SUPPLIER AGREEMENTS

2. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102, 1861, 1864(m), 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa(m), 1395cc, and 1395hh).

3. A new subpart I is added to read as follows:

Subpart I—Advance Directives

Sec.
489.100 Definition.
489.102 Requirements for providers.
489.104 Effective dates.

Subpart I—Advance Directives

§ 489.100 Definition.

For purposes of this part, "advance directive" means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.

§ 489.102 Requirements for providers.

(a) Hospitals, skilled nursing facilities, nursing facilities, home health agencies, providers of home health care (and for Medicaid purposes, providers of personal care services), and hospices must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the provider and are required to:

(1) Provide written information to such individuals concerning—

(i) An individual's rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives; and

(ii) The written policies of the provider or organization respecting the implementation of such rights, including a clear and precise statement of limitation if the provider cannot implement an advance directive on the basis of conscience;

(2) Document in the individual's medical record whether or not the individual has executed the implementation of such rights;

(3) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(4) Ensure compliance with requirements of State law (whether

statutory or recognized by the courts of the State) regarding advance directives;

(5) Provide for education of staff concerning its policies and procedures on advance directives; and

(6) Provide for community education regarding advance directives to include material required in paragraph (a)(1) of this section, either directly or in concert with other providers and organizations.

(b) The information specified in paragraph (a) of this section is furnished:

(1) In the case of a hospital, at the time of the individual's admission as an inpatient.

(2) In the case of a skilled nursing facility at the time of the individual's admission as a resident.

(3)(i) In the case of a home health agency, in advance of the individual coming under the care of the agency.

(ii) In the case of personal care services, in advance of the individual coming under the care of the personal care services provider.

(4) In the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program.

(c) The providers listed in paragraph (a) of this section—

(1) Are not required to provide care that conflicts with an advance directive.

(2) Are not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive, and State law allows any health care provider or any agency of such provider to conscientiously object.

(d) Prepaid or eligible organizations (as specified in sections 1833(a)(1)(A) and 1876(b) of the Act) must meet the requirements specified in § 417.436 of this chapter.

§ 489.104 Effective dates.

These provisions apply to services furnished on or after December 1, 1991 payments made under section 1833(a)(1)(A) of the Act on or after December 1, 1991, and contracts effective on or after December 1, 1991.

Subpart A—General Provisions

4.5 In subpart A, § 489.10 is amended by redesignating paragraph (b) as paragraph (c) and revising it and by adding a new paragraph (b) to read as follows:

§ 489.10 Basic requirements.

* * * * *

(b) In order for a hospital, SNF, HHA, or hospice to be accepted, it must also meet the advance directives requirements specified in Subpart I of this part.

(c) The State survey agency will ascertain whether the provider meets the conditions of participation or requirements (for SNFs) and make its recommendations to HCFA.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM

G. Part 498 is amended as follows:

1. The authority citation for part 498 is revised to read as follows:

Authority: Secs. 205(a), 1102, 1866(a), 1869(c), 1871 and 1872 of the Social Security Act (42 U.S.C. 405(a), 1302, 1395cc(a), 1395ff(c) 1395hh and 1395ii), unless otherwise noted.

2. In § 498.3(b), the introductory text is republished and a new paragraph (11) is added to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) *Initial determinations by HCFA.* HCFA makes initial determinations with respect to the following matters:

* * * * *

(11) Whether a hospital, skilled nursing facility, home health agency, or hospice program meets or contimues to meet the advance directives requirements specified in subpart I of part 489 of this chapter.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 92.773—Medicare—Hospital Insurance Program; No. 93.774—Medicare—Supplementary Medical Insurance Program; No. 93.778—Medical Assistance Programs.)

Dated: August 31, 1991.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: December 20, 1991.

Louis W. Sullivan,

Secretary.

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