interim final rule imposed information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These information collections require hospitals, nursing facilities, skilled nursing facilities, providers of home health care or personal care services, hospice programs and HMOs and CMPs to document in the medical record whether or not an individual has executed an advanced directive. We received several comments on our estimates of the collection burdens involved. The comments and our responses are presented in detail in section IV.A of the preamble to this final rule. OMB has approved the information collection requirements set forth in our March 6, 1992 interim final rule through June 30, 1996 (Approval Number 0938–610).

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Health maintenance organizations (HMOs), Medicare, Reporting and recordkeeping requirements.

42 CFR Part 430

Grants to States for Medical Assistance Programs.

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, Reporting and recordkeeping requirements.

42 CFR chapter IV is amended as follows:

A. Part 417 is amended as set forth below:

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

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

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

2. In § 417.436, the introductory text of paragraph (d)(1) is republished, paragraphs (d)(1)(i), (d)(1)(ii) and (d)(1)(vii) are revised, the introductory text of paragraph (d)(2) is republished, paragraph (d)(2)(ii) is revised, and paragraph (d)(3) is added to read as follows:

§ 417.436 Rules for enrollees.

* * * * *

(d) *Advance directives.* (1) An HMO or CMP 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 HMO or CMP and are required to:

(i) Provide written information to those individuals concerning—

(A) Their rights under the law of the State in which the organization furnishes services (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. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Such information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law; and

(B) The HMO's or CMP's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the HMO or CMP cannot implement an advance directive as a matter of conscience. At a minimum, this statement should:

(*1*) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;

(*2*) Identify the state legal authority permitting such objection; and

(*3*) Describe the range of medical conditions or procedures affected by the conscience objection.

(ii) Provide the information specified in paragraphs (d)(1)(i) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment 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, the HMO or CMP may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The HMO or CMP is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

* * * * *

(vii) Provide for community education regarding advance directives that may include material required in paragraph (d)(1)(i)(A) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the HMO or CMP. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An HMO or CMP must be able to document its community education efforts.

(2) The HMO or CMP—(i) * * *

(ii) Is not required to implement an advance directive if, as a matter of conscience, the HMO or CMP cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

(3) The HMO or CMP must inform individuals that complaints concerning non-compliance with the advance directive requirements may be filed with the State survey and certification agency.

B. Part 430 is amended as set forth below: