

NOTICE ACT

MARCH 13, 2015.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. RYAN of Wisconsin, from the Committee on Ways and Means, submitted the following

R E P O R T

[To accompany H.R. 876]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 876) to amend title XVIII of the Social Security Act to require hospitals to provide certain notifications to individuals classified by such hospitals under observation status rather than admitted as inpatients of such hospitals, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Notice of Observation Treatment and Implication for Care Eligibility Act” or the “NOTICE Act”.

SEC. 2. MEDICARE REQUIREMENT FOR HOSPITAL NOTIFICATIONS OF OBSERVATION STATUS.

Section 1866(a)(1) of the Social Security Act (42 U.S.C. 1395cc(a)(1)) is amended—

- (1) in subparagraph (V), by striking at the end “and”;
- (2) in the first subparagraph (W), by striking at the end the period and inserting a comma;
- (3) in the second subparagraph (W)—
 - (A) by redesignating such subparagraph as subparagraph (X); and
 - (B) by striking at the end the period and inserting “, and”; and
- (4) by inserting after such subparagraph (X) the following new subparagraph:

“(Y) beginning 12 months after the date of the enactment of this subparagraph, in the case of a hospital or critical access hospital, with respect to each individual who receives observation services as an outpatient at such hospital or critical access hospital for more than 24 hours, to provide to such individual not later than 36 hours after the time such individual begins receiving such services (or, if sooner, upon release)—

 - “(i) such oral explanation of the written notification described in clause (ii), and such documentation of the provision of such explanation, as the Secretary determines to be appropriate;
 - “(ii) a written notification (as specified by the Secretary pursuant to rule-making and containing such language as the Secretary prescribes consistent with this paragraph) which—
 - “(I) explains the status of the individual as an outpatient receiving observation services and not as an inpatient of the hospital or critical access hospital and the reasons for such status of such individual;
 - “(II) explains the implications of such status on services furnished by the hospital or critical access hospital (including services furnished on an inpatient basis), such as implications for cost-sharing requirements under this title and for subsequent eligibility for coverage under this title for services furnished by a skilled nursing facility;
 - “(III) includes such additional information as the Secretary determines appropriate;
 - “(IV) either—
 - “(aa) is signed by such individual or a person acting on such individual’s behalf to acknowledge receipt of such notification; or
 - “(bb) if such individual or person refuses to provide the signature described in item (aa), is signed by the staff member of the hospital or critical access hospital who presented the written notification and includes the name and title of such staff member, a certification that the notification was presented, and the date and time the notification was presented; and

“(V) is written and formatted using plain language and is made available in appropriate languages as determined by the Secretary.”.

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

The bill, H.R. 876, as ordered reported by the Committee on Ways and Means on February 26, 2015, is legislation to provide certainty to beneficiaries regarding their status as an outpatient under observation (or any similar status) and not as an inpatient. The Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) contains bipartisan policies, promoted by Ways and Means Committee members, that include the:

- Explanation for the reason for beneficiary’s classification as outpatient or inpatient
- Clarification on the implications of that outpatient status for beneficiaries on eligibility for Medicare coverage of items and services as well as cost-sharing requirements

- Name and title of the hospital staff who gave an oral notification and its date and time
- Requirement that the clarification be signed by the patient, if the notification is written, to acknowledge receipt, or if patient refuses to sign, the written notification is signed by the staff of the hospital who presented it

B. BACKGROUND AND THE NEED FOR LEGISLATION

On February 11, 2015, Representative Lloyd Doggett (D-TX), and Representative Todd Young (R-IN), introduced H.R. 876, which requires hospitals to provide certain notification to individuals classified by such hospitals under observation status rather than admitted as inpatients of such hospitals.

The NOTICE Act provides certainty to beneficiaries with regard to their classification as an inpatient or outpatient. Without the NOTICE Act, beneficiaries could be subject to costs they did not foresee due to their classification as either an outpatient under observation or an inpatient. By clarifying a beneficiary's status as either an outpatient under observation (or any similar status) or as an inpatient, the NOTICE Act will provide beneficiaries with accurate, real-time information with respect to their classification, the services and benefits available to them, and the respective cost-sharing requirements they are subject to.

C. LEGISLATIVE HISTORY

Background

H.R. 876 was introduced on February 11, 2015, and was referred to the Committee on Ways and Means, in addition to the Committee on Energy and Commerce. The bill was subsequently referred to the Subcommittee on Health.

Committee Action

The Committee on Ways and Means marked up the bill on February 26, 2015, and with a quorum present, ordered the bill favorably reported.

Committee Markups

On February 26, 2015, the Committee on Ways and Means held a markup of H.R. 876, "NOTICE Act", which was favorably reported to the House of Representatives by voice vote.

II. EXPLANATION OF THE BILL

PRESENT LAW

Current statute does not include requirements for beneficiary notification regarding their patient status.

REASONS FOR CHANGE

The Committee believes it is necessary to provide notice to beneficiaries regarding their status as either outpatient (or any similar status) or inpatient. In order to ensure the transparency, it is necessary for hospitals to notify patients of their status in order to prevent unanticipated cost sharing for services rendered.

The Committee believes that proper prior notification to patients will allow for the transmission of appropriate information to increase awareness of cost sharing requirements for services rendered. Ultimately, prior notification will allow patients to better anticipate their costs, create heightened clarity in the Medicare program, and reduce uncertainty to hospitals.

EXPLANATION OF PROVISION

The provision would require documentation, as the Secretary determines to be appropriate, to be provided to patients explaining the status of the patient as an outpatient receiving observation services and not as an inpatient of the hospital or critical access hospital (CAHs). Further, hospitals and CAHs must provide the reasons for such determination in order to increase the transparency to patients regarding his/her status within the Medicare program.

EFFECTIVE DATE

The provision becomes effective 12 months after the date of enactment.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statements are made concerning the votes of the Committee on Ways and Means in its consideration of the bill, H.R. 876.

The bill, H.R. 876, to amend title XVII of the Social Security Act to require hospitals to provide certain notifications to individuals classified by such hospitals under observation status rather than admitted as inpatients of such hospitals was ordered favorably reported with an amendment in the nature of a substitute to the House of Representatives by voice vote (with a quorum present).

VOTES ON AMENDMENTS

The amendment in the nature of a substitute was agreed to favorably by voice vote.

IV. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 3(d) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of the revenue provisions of the bill, H.R. 876 as reported: The Committee agrees with the estimates prepared by the Congressional Budget Office (CBO), which are included below.

B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES BUDGET AUTHORITY

The bill as reported is in compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives. Further, the bill involves no new or increased tax expenditures and no new budget authority.

C. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET
OFFICE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the CBO, the following statement by CBO is provided.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, March 11, 2015.

Hon. PAUL RYAN,
*Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 876, the Notice of Observation Treatment and Implication for Care Eligibility Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Erica Socker.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

*H.R. 876—Notice of Observation Treatment and Implication for
Care Eligibility Act*

H.R. 876 would require hospitals to notify Medicare beneficiaries receiving observation services for more than 24 hours of their status as an outpatient under observation. The written notification must explain that, because the beneficiary is receiving outpatient—rather than inpatient—services:

- The beneficiary will be subject to cost-sharing requirements that apply to outpatient services, and
- The beneficiary's outpatient stay will not count toward the three-day inpatient stay required for a beneficiary to be eligible for Medicare coverage of subsequent skilled nursing facility services.

Enacting H.R. 876 could affect direct spending; therefore, pay-as-you-go procedures apply. However, CBO estimates that the bill would not have significant budgetary effects over the 2015–2025 period.

H.R. 876 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local, or tribal governments.

The CBO staff contact for this estimate is Erica Socker. The estimate was approved by Holly Harvey, Deputy Assistant Director for Budget Analysis.

**V. OTHER MATTERS TO BE DISCUSSED UNDER THE
RULES OF THE HOUSE OF REPRESENTATIVES**

A. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

With respect to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives (relating to oversight findings), the Committee concluded that it was appropriate and timely to enact the sections included in the bill, as reported.

On May 20, 2014, the Subcommittee on Health held a hearing on current hospital issues in the Medicare program. During this hearing, the Subcommittee heard testimony from experts on the classification of patients as inpatient or outpatient and the resulting implication of patient cost sharing.

The Committee believes this legislation is necessary to ensure that patients are made aware of their status as outpatients (or any similar status) or as inpatients. This legislation is needed to ensure that patients are aware of their status in order to properly inform his/her cost-sharing status with regard to such classification.

B. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill contains no measure that authorizes new or additional funding compared with the current law baseline, so no statement of general performance goals and objectives for which any measure authorizes funding is required.

C. DUPLICATION OF FEDERAL PROGRAMS

In compliance with Sec. 3(g)(2) of H. Res. 5 (114th Congress), the Committee states that no provision of the bill establishes or reauthorizes: (1) a program of the Federal Government known to be duplicative of another Federal program, (2) a program included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111-139, or (3) a program related to a program identified in the most recent Catalog of Federal Domestic Assistance, published pursuant to the Federal Program Information Act (Public Law 95-220, as amended by Public Law 98-169).

D. DISCLOSURE OF DIRECTED RULE MAKINGS

In compliance with Sec. 3(i) of H. Res. 5 (114th Congress), the Committee estimates that H.R. 876 specifically directs the Secretary to complete rule-making on the change requiring changes in CMS policy regarding the notice to patients.

E. INFORMATION RELATING TO UNFUNDED MANDATES

This information is provided in accordance with section 423 of the Unfunded Mandates Act of 1995 (Pub. L. No. 104-4).

The bill does not impose a Federal mandate on the private sector. H.R. 876 does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

F. CONGRESSIONAL EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not contain any congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of the rule.

VI. Changes in Existing Law Made by the Bill, as Reported

With respect to clause 3(e) of rule XIII of the rules of the House of Representatives, H.R. 876 makes the following changes to current law.

CHANGES IN EXISTING LAW PROPOSED BY THE BILL, AS REPORTED

In compliance with clause 3(e)(1)(B) of rule XIII of the Rules of the House of Representatives, changes in existing law proposed by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * *

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

* * * * *

PART E—MISCELLANEOUS PROVISIONS

* * * * *

AGREEMENTS WITH PROVIDERS OF SERVICES; ENROLLMENT PROCESSES

SEC. 1866. (a)(1) Any provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement—

(A)(i) not to charge, except as provided in paragraph (2), any individual or any other person for items or services for which such individual is entitled to have payment made under this title (or for which he would be so entitled if such provider of services had complied with the procedural and other requirements under or pursuant to this title or for which such provider is paid pursuant to the provisions of section 1814(e)), and (ii) not to impose any charge that is prohibited under section 1902(n)(3),

(B) not to charge any individual or any other person for items or services for which such individual is not entitled to have payment made under this title because payment for expenses incurred for such items or services may not be made by reason of the provisions of paragraph (1) or (9) of section 1862(a), but only if (i) such individual was without fault in incurring such expenses and (ii) the Secretary's determination that such payment may not be made for such items and services was made after the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title,

(C) to make adequate provision for return (or other disposition, in accordance with regulations) of any moneys incorrectly collected from such individual or other person,

(D) to promptly notify the Secretary of its employment of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity (as determined by the Secretary by regulation) by an agency or organization which serves as a fiscal intermediary or carrier (for purposes of part A or part B, or both, of this title) with respect to the provider,

(E) to release data with respect to patients of such provider upon request to an organization having a contract with the Secretary under part B of title XI as may be necessary (i) to allow such organization to carry out its functions under such contract, or (ii) to allow such organization to carry out similar review functions under any contract the organization may have with a private or public agency paying for health care in the same area with respect to patients who authorize release of such data for such purposes,

(F)(i) in the case of hospitals which provide inpatient hospital services for which payment may be made under subsection (b), (c), or (d) of section 1886, to maintain an agreement with a professional standards review organization (if there is such an organization in existence in the area in which the hospital is located) or with a quality improvement organization which has a contract with the Secretary under part B of title XI for the area in which the hospital is located, under which the organization will perform functions under that part with respect to the review of the validity of diagnostic information provided by such hospital, the completeness, adequacy, and quality of care provided, the appropriateness of admissions and discharges, and the appropriateness of care provided for which additional payments are sought under section 1886(d)(5), with respect to inpatient hospital services for which payment may be made under part A of this title (and for purposes of payment under this title, the cost of such agreement to the hospital shall be considered a cost incurred by such hospital in providing inpatient services under part A, and (I) shall be paid directly by the Secretary to such organization on behalf of such hospital in accordance with a rate per review established by the Secretary, (II) shall be transferred from the Federal Hospital Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and (III) shall not be less in the aggregate for a fiscal year than the aggregate amount expended in fiscal year 1988 for direct and administrative costs (adjusted for inflation and for any direct or administrative costs incurred as a result of review functions added with respect to a subsequent fiscal year) of such reviews),

(ii) in the case of hospitals, critical access hospitals, skilled nursing facilities, and home health agencies, to maintain an agreement with a quality improvement organization (which has a contract with the Secretary under part B of title XI for

the area in which the hospital, facility, or agency is located) to perform the functions described in paragraph (3)(A),

(G) in the case of hospitals which provide inpatient hospital services for which payment may be made under subsection (b) or (d) of section 1886, not to charge any individual or any other person for inpatient hospital services for which such individual would be entitled to have payment made under part A but for a denial or reduction of payments under section 1886(f)(2),

(H)(i) in the case of hospitals which provide services for which payment may be made under this title and in the case of critical access hospitals which provide critical access hospital services, to have all items and services (other than physicians' services as defined in regulations for purposes of section 1862(a)(14), and other than services described by section 1861(s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist) (I) that are furnished to an individual who is a patient of the hospital, and (II) for which the individual is entitled to have payment made under this title, furnished by the hospital or otherwise under arrangements (as defined in section 1861(w)(1)) made by the hospital,

(ii) in the case of skilled nursing facilities which provide covered skilled nursing facility services—

(I) that are furnished to an individual who is a resident of the skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1861(s)(2)(D), that are furnished to such an individual without regard to such period), and

(II) for which the individual is entitled to have payment made under this title,

to have items and services (other than services described in section 1888(e)(2)(A)(ii)) furnished by the skilled nursing facility or otherwise under arrangements (as defined in section 1861(w)(1)) made by the skilled nursing facility,

(I) in the case of a hospital or critical access hospital—

(i) to adopt and enforce a policy to ensure compliance with the requirements of section 1867 and to meet the requirements of such section,

(ii) to maintain medical and other records related to individuals transferred to or from the hospital for a period of five years from the date of the transfer, and

(iii) to maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition,

(J) in the case of hospitals which provide inpatient hospital services for which payment may be made under this title, to be a participating provider of medical care under any health plan contracted for under section 1079 or 1086 of title 10, or under section 613 of title 38, United States Code, in accordance with admission practices, payment methodology, and amounts as prescribed under joint regulations issued by the Secretary and by the Secretaries of Defense and Transportation, in im-

plementation of sections 1079 and 1086 of title 10, United States Code,

(K) not to charge any individual or any other person for items or services for which payment under this title is denied under section 1154(a)(2) by reason of a determination under section 1154(a)(1)(B),

(L) in the case of hospitals which provide inpatient hospital services for which payment may be made under this title, to be a participating provider of medical care under section 603 of title 38, United States Code, in accordance with such admission practices, and such payment methodology and amounts, as are prescribed under joint regulations issued by the Secretary and by the Secretary of Veterans Affairs in implementation of such section,

(M) in the case of hospitals, to provide to each individual who is entitled to benefits under part A (or to a person acting on the individual's behalf), at or about the time of the individual's admission as an inpatient to the hospital, a written statement (containing such language as the Secretary prescribes consistent with this paragraph) which explains—

(i) the individual's rights to benefits for inpatient hospital services and for post-hospital services under this title,

(ii) the circumstances under which such an individual will and will not be liable for charges for continued stay in the hospital,

(iii) the individual's right to appeal denials of benefits for continued inpatient hospital services, including the practical steps to initiate such an appeal, and

(iv) the individual's liability for payment for services if such a denial of benefits is upheld on appeal,—and which provides such additional information as the Secretary may specify,

(N) in the case of hospitals and critical access hospitals—

(i) to make available to its patients the directory or directories of participating physicians (published under section 1842(h)(4)) for the area served by the hospital or critical access hospital,

(ii) if hospital personnel (including staff of any emergency or outpatient department) refer a patient to a nonparticipating physician for further medical care on an outpatient basis, the personnel must inform the patient that the physician is a nonparticipating physician and, whenever practicable, must identify at least one qualified participating physician who is listed in such a directory and from whom the patient may receive the necessary services,

(iii) to post conspicuously in any emergency department a sign (in a form specified by the Secretary) specifying rights of individuals under section 1867 with respect to examination and treatment for emergency medical conditions and women in labor, and

(iv) to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital participates in the medicaid program under a State plan approved under title XIX,

(O) to accept as payment in full for services that are covered under this title and are furnished to any individual enrolled with a Medicare+Choice organization under part C, with a PACE provider under section 1894 or 1934, or with an eligible organization with a risk-sharing contract under section 1876, under section 1876(i)(2)(A) (as in effect before February 1, 1985), under section 402(a) of the Social Security Amendments of 1967, or under section 222(a) of the Social Security Amendments of 1972, which does not have a contract (or, in the case of a PACE provider, contract or other agreement) establishing payment amounts for services furnished to members of the organization or PACE program eligible individuals enrolled with the PACE provider, the amounts that would be made as a payment in full under this title (less any payments under sections 1886(d)(11) and 1886(h)(3)(D)) if the individuals were not so enrolled,

(P) in the case of home health agencies which provide home health services to individuals entitled to benefits under this title who require catheters, catheter supplies, ostomy bags, and supplies related to ostomy care (described in section 1861(m)(5)), to offer to furnish such supplies to such an individual as part of their furnishing of home health services,

(Q) in the case of hospitals, skilled nursing facilities, home health agencies, and hospice programs, to comply with the requirement of subsection (f) (relating to maintaining written policies and procedures respecting advance directives),

(R) to contract only with a health care clearinghouse (as defined in section 1171) that meets each standard and implementation specification adopted or established under part C of title XI on or after the date on which the health care clearinghouse is required to comply with the standard or specification,

(S) in the case of a hospital that has a financial interest (as specified by the Secretary in regulations) in an entity to which individuals are referred as described in section 1861(ee)(2)(H)(ii), or in which such an entity has such a financial interest, or in which another entity has such a financial interest (directly or indirectly) with such hospital and such an entity, to maintain and disclose to the Secretary (in a form and manner specified by the Secretary) information on—

(i) the nature of such financial interest,

(ii) the number of individuals who were discharged from the hospital and who were identified as requiring home health services, and

(iii) the percentage of such individuals who received such services from such provider (or another such provider),

(T) in the case of hospitals and critical access hospitals, to furnish to the Secretary such data as the Secretary determines appropriate pursuant to subparagraph (E) of section 1886(d)(12) to carry out such section,

(U) in the case of hospitals which furnish inpatient hospital services for which payment may be made under this title, to be a participating provider of medical care both—

(i) under the contract health services program funded by the Indian Health Service and operated by the Indian Health Service, an Indian tribe, or tribal organization (as

those terms are defined in section 4 of the Indian Health Care Improvement Act), with respect to items and services that are covered under such program and furnished to an individual eligible for such items and services under such program; and

(ii) under any program funded by the Indian Health Service and operated by an urban Indian organization with respect to the purchase of items and services for an eligible urban Indian (as those terms are defined in such section 4),

in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodology, and rates of payment (including the acceptance of no more than such payment rate as payment in full for such items and services,

(V) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 (or a State occupational safety and health plan that is approved under 18(b) of such Act), to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated), **[and]**

(W) in the case of a hospital described in section 1886(d)(1)(B)(v), to report quality data to the Secretary in accordance with subsection (k)**[.].**

[(W)] (X) maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider under this title, as specified by the Secretary**[.], and**

(Y) beginning 12 months after the date of the enactment of this subparagraph, in the case of a hospital or critical access hospital, with respect to each individual who receives observation services as an outpatient at such hospital or critical access hospital for more than 24 hours, to provide to such individual not later than 36 hours after the time such individual begins receiving such services (or, if sooner, upon release)—

(i) such oral explanation of the written notification described in clause (ii), and such documentation of the provision of such explanation, as the Secretary determines to be appropriate;

(ii) a written notification (as specified by the Secretary pursuant to rulemaking and containing such language as the Secretary prescribes consistent with this paragraph) which—

(I) explains the status of the individual as an outpatient receiving observation services and not as an inpatient of the hospital or critical access hospital and the reasons for such status of such individual;

(II) explains the implications of such status on services furnished by the hospital or critical access hospital (including services furnished on an inpatient basis), such as implications for cost-sharing requirements under this title and for subsequent eligibility for cov-

erage under this title for services furnished by a skilled nursing facility;

(III) includes such additional information as the Secretary determines appropriate;

(IV) either—

(aa) is signed by such individual or a person acting on such individual's behalf to acknowledge receipt of such notification; or

(bb) if such individual or person refuses to provide the signature described in item (aa), is signed by the staff member of the hospital or critical access hospital who presented the written notification and includes the name and title of such staff member, a certification that the notification was presented, and the date and time the notification was presented; and

(V) is written and formatted using plain language and is made available in appropriate languages as determined by the Secretary.

In the case of a hospital which has an agreement in effect with an organization described in subparagraph (F), which organization's contract with the Secretary under part B of title XI is terminated on or after October 1, 1984, the hospital shall not be determined to be out of compliance with the requirement of such subparagraph during the six month period beginning on the date of the termination of that contract.

(2)(A) A provider of services may charge such individual or other person (i) the amount of any deduction or coinsurance amount imposed pursuant to section 1813(a)(1), (a)(3), or (a)(4), section 1833(b), or section 1861(y)(3) with respect to such items and services (not in excess of the amount customarily charged for such items and services by such provider), and (ii) an amount equal to 20 per centum of the reasonable charges for such items and services (not in excess of 20 per centum of the amount customarily charged for such items and services by such provider) for which payment is made under part B or which are durable medical equipment furnished as home health services (but in the case of items and services furnished to individuals with end-stage renal disease, an amount equal to 20 percent of the estimated amounts for such items and services calculated on the basis established by the Secretary). In the case of items and services described in section 1833(c), clause (ii) of the preceding sentence shall be applied by substituting for 20 percent the proportion which is appropriate under such section. A provider of services may not impose a charge under clause (ii) of the first sentence of this subparagraph with respect to items and services described in section 1861(s)(10)(A) and with respect to clinical diagnostic laboratory tests for which payment is made under part B. Notwithstanding the first sentence of this subparagraph, a home health agency may charge such an individual or person, with respect to covered items subject to payment under section 1834(a), the amount of any deduction imposed under section 1833(b) and 20 percent of the payment basis described in section 1834(a)(1)(B). In the case of items and services for which payment is made under part B under the prospective payment system established under section 1833(t), clause (ii) of the first sen-

tence shall be applied by substituting for 20 percent of the reasonable charge, the applicable copayment amount established under section 1833(t)(5). In the case of services described in section 1833(a)(8) or section 1833(a)(9) for which payment is made under part B under section 1834(k), clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge for such services 20 percent of the lesser of the actual charge or the applicable fee schedule amount (as defined in such section) for such services.

(B) Where a provider of services has furnished, at the request of such individual, items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under this title, such provider of services may also charge such individual or other person for such more expensive items or services to the extent that the amount customarily charged by it for the items or services furnished at such request exceeds the amount customarily charged by it for the items or services with respect to which payment may be made under this title.

(C) A provider of services may in accordance with its customary practice also appropriately charge any such individual for any whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished him with respect to which a deductible is imposed under section 1813(a)(2), except that (i) any excess of such charge over the cost to such provider for the blood (or equivalent quantities of packed red blood cells, as so defined) shall be deducted from any payment to such provider under this title, (ii) no such charge may be imposed for the cost of administration of such blood (or equivalent quantities of packed red blood cells, as so defined), and (iii) such charge may not be made to the extent such blood (or equivalent quantities of packed red blood cells, as so defined) has been replaced on behalf of such individual or arrangements have been made for its replacement on his behalf. For purposes of subparagraph (C), whole blood (or equivalent quantities of packed red blood cells, as so defined) furnished an individual shall be deemed replaced when the provider of services is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is imposed under section 1813(a)(2).

(D) Where a provider of services customarily furnishes items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under this title, such provider, notwithstanding the preceding provisions of this paragraph, may not, under the authority of section 1866(a)(2)(B)(ii), charge any individual or other person any amount for such items or services in excess of the amount of the payment which may otherwise be made for such items or services under this title if the admitting physician has a direct or indirect financial interest in such provider.

(3)(A) Under the agreement required under paragraph (1)(F)(ii), the quality improvement organization must perform functions (other than those covered under an agreement under paragraph (1)(F)(i)) under the third sentence of section 1154(a)(4)(A) and under section 1154(a)(14) with respect to services, furnished by the

hospital, critical access hospital, facility, or agency involved, for which payment may be made under this title.

(B) For purposes of payment under this title, the cost of such an agreement to the hospital, critical access hospital, facility, or agency shall be considered a cost incurred by such hospital, critical access hospital, facility, or agency in providing covered services under this title and shall be paid directly by the Secretary to the quality improvement organization on behalf of such hospital, critical access hospital, facility, or agency in accordance with a schedule established by the Secretary.

(C) Such payments—

(i) shall be transferred in appropriate proportions from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and

(ii) shall not be less in the aggregate for a fiscal year—

(I) in the case of hospitals, than the amount specified in paragraph (1)(F)(i)(III), and

(II) in the case of facilities, critical access hospitals, and agencies, than the amounts the Secretary determines to be sufficient to cover the costs of such organizations' conducting the activities described in subparagraph (A) with respect to such facilities, critical access hospitals, or agencies under part B of title XI.

(b)(1) A provider of services may terminate an agreement with the Secretary under this section at such time and upon such notice to the Secretary and the public as may be provided in regulations, except that notice of more than six months shall not be required.

(2) The Secretary may refuse to enter into an agreement under this section or, upon such reasonable notice to the provider and the public as may be specified in regulations, may refuse to renew or may terminate such an agreement after the Secretary—

(A) has determined that the provider fails to comply substantially with the provisions of the agreement, with the provisions of this title and regulations thereunder, or with a corrective action required under section 1886(f)(2)(B),

(B) has determined that the provider fails substantially to meet the applicable provisions of section 1861,

(C) has excluded the provider from participation in a program under this title pursuant to section 1128 or section 1128A, or

(D) has ascertained that the provider has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries.

(3) A termination of an agreement or a refusal to renew an agreement under this subsection shall become effective on the same date and in the same manner as an exclusion from participation under the programs under this title becomes effective under section 1128(c).

(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(V) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in

subparagraph (B), but is not subject to termination of an agreement under this section.

(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(U) by a hospital that is subject to the provisions of such Act.

(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

(c)(1) Where the Secretary has terminated or has refused to renew an agreement under this title with a provider of services, such provider may not file another agreement under this title unless the Secretary finds that the reason for the termination or nonrenewal has been removed and that there is reasonable assurance that it will not recur.

(2) Where the Secretary has terminated or has refused to renew an agreement under this title with a provider of services, the Secretary shall promptly notify each State agency which administers or supervises the administration of a State plan approved under title XIX of such termination or nonrenewal.

(d) If the Secretary finds that there is a substantial failure to make timely review in accordance with section 1861(k) of long-stay cases in a hospital, he may, in lieu of terminating his agreement with such hospital, decide that, with respect to any individual admitted to such hospital after a subsequent date specified by him, no payment shall be made under this title for inpatient hospital services (including inpatient psychiatric hospital services) after the 20th day of a continuous period of such services. Such decision may be made effective only after such notice to the hospital and to the public, as may be prescribed by regulations, and its effectiveness shall terminate when the Secretary finds that the reason therefor has been removed and that there is reasonable assurance that it will not recur. The Secretary shall not make any such decision except after reasonable notice and opportunity for hearing to the institution or agency affected thereby.

(e) For purposes of this section, the term "provider of services" shall include—

(1) a clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1861(p)(4)(A) (or meets the requirements of such section through the operation of subsection (g) or (ll)(2) of section 1861), or if, in the case of a public health agency, such agency meets the requirements of section 1861(p)(4)(B) (or meets the requirements of such section through the operation of subsection (g) or (ll)(2) of section 1861), but only with respect to the furnishing of outpatient physical therapy services (as therein defined), (through the operation of section 1861(g)) with respect to the furnishing of outpatient occupational therapy services, or (through the operation of section 1861(ll)(2)) with respect to the furnishing of outpatient speech-language pathology; and

(2) a community mental health center (as defined in section 1861(ff)(3)(B)), but only with respect to the furnishing of partial hospitalization services (as described in section 1861(ff)(1)).

(f)(1) For purposes of subsection (a)(1)(Q) and sections 1819(c)(2)(E), 1833(s), 1855(i), 1876(c)(8), and 1891(a)(6), the requirement of this subsection is that a provider of services, Medicare+Choice organization, or prepaid or eligible organization (as the case may be) maintain written policies and procedures with respect to all adult individuals receiving medical care by or through the provider or organization—

(A) to provide written information to each such individual concerning—

(i) an individual's rights under State law (whether statutory or as 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 advance directives (as defined in paragraph (3)), and

(ii) the written policies of the provider or organization respecting the implementation of such rights;

(B) to document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive;

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

(D) to ensure compliance with requirements of State law (whether statutory or as recognized by the courts of the State) respecting advance directives at facilities of the provider or organization; and

(E) to provide (individually or with others) for education for staff and the community on issues concerning advance directives.

Subparagraph (C) shall not be construed as requiring the provision of care which conflicts with an advance directive.

(2) The written information described in paragraph (1)(A) shall be provided to an adult individual—

(A) in the case of a hospital, at the time of the individual's admission as an inpatient,

(B) in the case of a skilled nursing facility, at the time of the individual's admission as a resident,

(C) in the case of a home health agency, in advance of the individual coming under the care of the agency,

(D) in the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program, and

(E) in the case of an eligible organization (as defined in section 1876(b)) or an organization provided payments under section 1833(a)(1)(A) or a Medicare+Choice organization, at the time of enrollment of the individual with the organization.

(3) In this subsection, the term "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) and relating to the provision of such care when the individual is incapacitated.

(4) For construction relating to this subsection, see section 7 of the Assisted Suicide Funding Restriction Act of 1997 (relating to clarification respecting assisted suicide, euthanasia, and mercy killing).

(g) Except as permitted under subsection (a)(2), any person who knowingly and willfully presents, or causes to be presented, a bill or request for payment inconsistent with an arrangement under subsection (a)(1)(H) or in violation of the requirement for such an arrangement, is subject to a civil money penalty of not to exceed \$2,000. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(h)(1)(A) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or with a determination described in subsection (b)(2) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g), except that, in so applying such sections and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.

(C)(i) The Secretary shall develop and implement a process to expedite proceedings under this subsection in which—

(I) the remedy of termination of participation has been imposed;

(II) a remedy described in clause (i) or (iii) of section 1819(h)(2)(B) has been imposed, but only if such remedy has been imposed on an immediate basis; or

(III) a determination has been made as to a finding of substandard quality of care that results in the loss of approval of a skilled nursing facility's nurse aide training program.

(ii) Under such process under clause (i), priority shall be provided in cases of termination described in clause (i)(I).

(iii) Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.

(2) An institution or agency is not entitled to separate notice and opportunity for a hearing under both section 1128 and this section with respect to a determination or determinations based on the same underlying facts and issues.

(i)(1) If the Secretary determines that a psychiatric hospital which has an agreement in effect under this section no longer meets the requirements for a psychiatric hospital under this title and further finds that the hospital's deficiencies—

(A) immediately jeopardize the health and safety of its patients, the Secretary shall terminate such agreement; or

(B) do not immediately jeopardize the health and safety of its patients, the Secretary may terminate such agreement, or provide that no payment will be made under this title with respect to any individual admitted to such hospital after the effective date of the finding, or both.

(2) If a psychiatric hospital, found to have deficiencies described in paragraph (1)(B), has not complied with the requirements of this title—

(A) within 3 months after the date the hospital is found to be out of compliance with such requirements, the Secretary shall provide that no payment will be made under this title with respect to any individual admitted to such hospital after the end of such 3-month period, or

(B) within 6 months after the date the hospital is found to be out of compliance with such requirements, no payment may be made under this title with respect to any individual in the hospital until the Secretary finds that the hospital is in compliance with the requirements of this title.

(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) ENROLLMENT PROCESS.—

(A) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title. Such process shall include screening of providers and suppliers in accordance with paragraph (2), a provisional period of enhanced oversight in accordance with paragraph (3), disclosure requirements in accordance with paragraph (4), the imposition of temporary enrollment moratoria in accordance with paragraph (5), and the establishment of compliance programs in accordance with paragraph (6).

(B) DEADLINES.—The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under this subparagraph.

(C) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this title.

(2) PROVIDER SCREENING.—

(A) PROCEDURES.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish procedures under which screening is conducted with respect to pro-

viders of medical or other items or services and suppliers under the program under this title, the Medicaid program under title XIX, and the CHIP program under title XXI.

(B) LEVEL OF SCREENING.—The Secretary shall determine the level of screening conducted under this paragraph according to the risk of fraud, waste, and abuse, as determined by the Secretary, with respect to the category of provider of medical or other items or services or supplier. Such screening—

(i) shall include a licensure check, which may include such checks across States; and

(ii) may, as the Secretary determines appropriate based on the risk of fraud, waste, and abuse described in the preceding sentence, include—

(I) a criminal background check;

(II) fingerprinting;

(III) unscheduled and unannounced site visits, including preenrollment site visits;

(IV) database checks (including such checks across States); and

(V) such other screening as the Secretary determines appropriate.

(C) APPLICATION FEES.—

(i) INSTITUTIONAL PROVIDERS.—Except as provided in clause (ii), the Secretary shall impose a fee on each institutional provider of medical or other items or services or supplier (such as a hospital or skilled nursing facility) with respect to which screening is conducted under this paragraph in an amount equal to—

(I) for 2010, \$500; and

(II) for 2011 and each subsequent year, the amount determined under this clause for the preceding year, adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year.

(ii) HARDSHIP EXCEPTION; WAIVER FOR CERTAIN MEDICAID PROVIDERS.—The Secretary may, on a case-by-case basis, exempt a provider of medical or other items or services or supplier from the imposition of an application fee under this subparagraph if the Secretary determines that the imposition of the application fee would result in a hardship. The Secretary may waive the application fee under this subparagraph for providers enrolled in a State Medicaid program for whom the State demonstrates that imposition of the fee would impede beneficiary access to care.

(iii) USE OF FUNDS.—Amounts collected as a result of the imposition of a fee under this subparagraph shall be used by the Secretary for program integrity efforts, including to cover the costs of conducting screening under this paragraph and to carry out this subsection and section 1128J.

(D) APPLICATION AND ENFORCEMENT.—

(i) NEW PROVIDERS OF SERVICES AND SUPPLIERS.—The screening under this paragraph shall apply, in the case of a provider of medical or other items or services or supplier who is not enrolled in the program under this title, title XIX, or title XXI as of the date of enactment of this paragraph, on or after the date that is 1 year after such date of enactment.

(ii) CURRENT PROVIDERS OF SERVICES AND SUPPLIERS.—The screening under this paragraph shall apply, in the case of a provider of medical or other items or services or supplier who is enrolled in the program under this title, title XIX, or title XXI as of such date of enactment, on or after the date that is 2 years after such date of enactment.

(iii) REVALIDATION OF ENROLLMENT.—Effective beginning on the date that is 180 days after such date of enactment, the screening under this paragraph shall apply with respect to the revalidation of enrollment of a provider of medical or other items or services or supplier in the program under this title, title XIX, or title XXI.

(iv) LIMITATION ON ENROLLMENT AND REVALIDATION OF ENROLLMENT.—In no case may a provider of medical or other items or services or supplier who has not been screened under this paragraph be initially enrolled or reenrolled in the program under this title, title XIX, or title XXI on or after the date that is 3 years after such date of enactment.

(E) USE OF INFORMATION FROM THE DEPARTMENT OF TREASURY CONCERNING TAX DEBTS.—In reviewing the application of a provider of services or supplier to enroll or reenroll under the program under this title, the Secretary shall take into account the information supplied by the Secretary of the Treasury pursuant to section 6103(1)(22) of the Internal Revenue Code of 1986, in determining whether to deny such application or to apply enhanced oversight to such provider of services or supplier pursuant to paragraph (3) if the Secretary determines such provider of services or supplier owes such a debt.

(F) EXPEDITED RULEMAKING.—The Secretary may promulgate an interim final rule to carry out this paragraph.

(3) PROVISIONAL PERIOD OF ENHANCED OVERSIGHT FOR NEW PROVIDERS OF SERVICES AND SUPPLIERS.—

(A) IN GENERAL.—The Secretary shall establish procedures to provide for a provisional period of not less than 30 days and not more than 1 year during which new providers of medical or other items or services and suppliers, as the Secretary determines appropriate, including categories of providers or suppliers, would be subject to enhanced oversight, such as prepayment review and payment caps, under the program under this title, the Medicaid program under title XIX, and the CHIP program under title XXI.

(B) IMPLEMENTATION.—The Secretary may establish by program instruction or otherwise the procedures under this paragraph.

(4) 90-DAY PERIOD OF ENHANCED OVERSIGHT FOR INITIAL CLAIMS OF DME SUPPLIERS.—For periods beginning after January 1, 2011, if the Secretary determines that there is a significant risk of fraudulent activity among suppliers of durable medical equipment, in the case of a supplier of durable medical equipment who is within a category or geographic area under title XVIII identified pursuant to such determination and who is initially enrolling under such title, the Secretary shall, notwithstanding sections 1816(c), 1842(c), and 1869(a)(2), withhold payment under such title with respect to durable medical equipment furnished by such supplier during the 90-day period beginning on the date of the first submission of a claim under such title for durable medical equipment furnished by such supplier.

(5) INCREASED DISCLOSURE REQUIREMENTS.—

(A) DISCLOSURE.—A provider of medical or other items or services or supplier who submits an application for enrollment or revalidation of enrollment in the program under this title, title XIX, or title XXI on or after the date that is 1 year after the date of enactment of this paragraph shall disclose (in a form and manner and at such time as determined by the Secretary) any current or previous affiliation (directly or indirectly) with a provider of medical or other items or services or supplier that has uncollected debt, has been or is subject to a payment suspension under a Federal health care program (as defined in section 1128B(f)), has been excluded from participation under the program under this title, the Medicaid program under title XIX, or the CHIP program under title XXI, or has had its billing privileges denied or revoked.

(B) AUTHORITY TO DENY ENROLLMENT.—If the Secretary determines that such previous affiliation poses an undue risk of fraud, waste, or abuse, the Secretary may deny such application. Such a denial shall be subject to appeal in accordance with paragraph (7).

(6) AUTHORITY TO ADJUST PAYMENTS OF PROVIDERS OF SERVICES AND SUPPLIERS WITH THE SAME TAX IDENTIFICATION NUMBER FOR MEDICARE OBLIGATIONS.—

(A) IN GENERAL.—Notwithstanding any other provision of this title, in the case of an applicable provider of services or supplier, the Secretary may make any necessary adjustments to payments to the applicable provider of services or supplier under the program under this title in order to satisfy any amount described in subparagraph (B)(ii) due from such obligated provider of services or supplier.

(B) DEFINITIONS.—In this paragraph:

(i) IN GENERAL.—The term “applicable provider of services or supplier” means a provider of services or supplier that has the same taxpayer identification number assigned under section 6109 of the Internal Revenue Code of 1986 as is assigned to the obligated

provider of services or supplier under such section, regardless of whether the applicable provider of services or supplier is assigned a different billing number or national provider identification number under the program under this title than is assigned to the obligated provider of services or supplier.

(ii) OBLIGATED PROVIDER OF SERVICES OR SUPPLIER.—The term “obligated provider of services or supplier” means a provider of services or supplier that owes an amount that is more than the amount required to be paid under the program under this title (as determined by the Secretary).

(7) TEMPORARY MORATORIUM ON ENROLLMENT OF NEW PROVIDERS.—

(A) IN GENERAL.—The Secretary may impose a temporary moratorium on the enrollment of new providers of services and suppliers, including categories of providers of services and suppliers, in the program under this title, under the Medicaid program under title XIX, or under the CHIP program under title XXI if the Secretary determines such moratorium is necessary to prevent or combat fraud, waste, or abuse under either such program.

(B) LIMITATION ON REVIEW.—There shall be no judicial review under section 1869, section 1878, or otherwise, of a temporary moratorium imposed under subparagraph (A).

(8) COMPLIANCE PROGRAMS.—

(A) IN GENERAL.—On or after the date of implementation determined by the Secretary under subparagraph (C), a provider of medical or other items or services or supplier within a particular industry sector or category shall, as a condition of enrollment in the program under this title, title XIX, or title XXI, establish a compliance program that contains the core elements established under subparagraph (B) with respect to that provider or supplier and industry or category.

(B) ESTABLISHMENT OF CORE ELEMENTS.—The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish core elements for a compliance program under subparagraph (A) for providers or suppliers within a particular industry or category.

(C) TIMELINE FOR IMPLEMENTATION.—The Secretary shall determine the timeline for the establishment of the core elements under subparagraph (B) and the date of the implementation of subparagraph (A) for providers or suppliers within a particular industry or category. The Secretary shall, in determining such date of implementation, consider the extent to which the adoption of compliance programs by a provider of medical or other items or services or supplier is widespread in a particular industry sector or with respect to a particular provider or supplier category.

(8) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is de-

nied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.

(k) QUALITY REPORTING BY CANCER HOSPITALS.—

(1) IN GENERAL.—For purposes of fiscal year 2014 and each subsequent fiscal year, a hospital described in section 1886(d)(1)(B)(v) shall submit data to the Secretary in accordance with paragraph (2) with respect to such a fiscal year.

(2) SUBMISSION OF QUALITY DATA.—For fiscal year 2014 and each subsequent fiscal year, each hospital described in such section shall submit to the Secretary data on quality measures specified under paragraph (3). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(3) QUALITY MEASURES.—

(A) IN GENERAL.—Subject to subparagraph (B), any measure specified by the Secretary under this paragraph must have been endorsed by the entity with a contract under section 1890(a).

(B) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(C) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this paragraph that will be applicable with respect to fiscal year 2014.

(4) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under paragraph (4) available to the public. Such procedures shall ensure that a hospital described in section 1886(d)(1)(B)(v) has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

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TEXT OF EXISTING LAW AMENDED OR REPEALED BY THE BILL, AS REPORTED

In compliance with clause 3(e)(1)(A) of rule XIII of the Rules of the House of Representatives, the text of each section proposed to be amended or repealed by the bill, as reported, is shown below:

SOCIAL SECURITY ACT

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**TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND
DISABLED**

* * * * * *

PART E—MISCELLANEOUS PROVISIONS

* * * * * *

**AGREEMENTS WITH PROVIDERS OF SERVICES; ENROLLMENT
PROCESSES**

SEC. 1866. (a)(1) Any provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement—

(A)(i) not to charge, except as provided in paragraph (2), any individual or any other person for items or services for which such individual is entitled to have payment made under this title (or for which he would be so entitled if such provider of services had complied with the procedural and other requirements under or pursuant to this title or for which such provider is paid pursuant to the provisions of section 1814(e)), and (ii) not to impose any charge that is prohibited under section 1902(n)(3),

(B) not to charge any individual or any other person for items or services for which such individual is not entitled to have payment made under this title because payment for expenses incurred for such items or services may not be made by reason of the provisions of paragraph (1) or (9) of section 1862(a), but only if (i) such individual was without fault in incurring such expenses and (ii) the Secretary's determination that such payment may not be made for such items and services was made after the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title,

(C) to make adequate provision for return (or other disposition, in accordance with regulations) of any moneys incorrectly collected from such individual or other person,

(D) to promptly notify the Secretary of its employment of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity (as determined by the Secretary by regulation) by an agency or organization which serves as a fiscal intermediary or carrier (for purposes of part A or part B, or both, of this title) with respect to the provider,

(E) to release data with respect to patients of such provider upon request to an organization having a contract with the Secretary under part B of title XI as may be necessary (i) to allow such organization to carry out its functions under such contract, or (ii) to allow such organization to carry out similar review functions under any contract the organization may have with a private or public agency paying for health care in the same area with respect to patients who authorize release of such data for such purposes,

(F)(i) in the case of hospitals which provide inpatient hospital services for which payment may be made under subsection (b), (c), or (d) of section 1886, to maintain an agreement with a professional standards review organization (if there is such an organization in existence in the area in which the hospital is located) or with a quality improvement organization which has a contract with the Secretary under part B of title XI for the area in which the hospital is located, under which the organization will perform functions under that part with respect to the review of the validity of diagnostic information provided by such hospital, the completeness, adequacy, and quality of care provided, the appropriateness of admissions and discharges, and the appropriateness of care provided for which additional payments are sought under section 1886(d)(5), with respect to inpatient hospital services for which payment may be made under part A of this title (and for purposes of payment under this title, the cost of such agreement to the hospital shall be considered a cost incurred by such hospital in providing inpatient services under part A, and (I) shall be paid directly by the Secretary to such organization on behalf of such hospital in accordance with a rate per review established by the Secretary, (II) shall be transferred from the Federal Hospital Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and (III) shall not be less in the aggregate for a fiscal year than the aggregate amount expended in fiscal year 1988 for direct and administrative costs (adjusted for inflation and for any direct or administrative costs incurred as a result of review functions added with respect to a subsequent fiscal year) of such reviews),

(ii) in the case of hospitals, critical access hospitals, skilled nursing facilities, and home health agencies, to maintain an agreement with a quality improvement organization (which has a contract with the Secretary under part B of title XI for the area in which the hospital, facility, or agency is located) to perform the functions described in paragraph (3)(A),

(G) in the case of hospitals which provide inpatient hospital services for which payment may be made under subsection (b) or (d) of section 1886, not to charge any individual or any other person for inpatient hospital services for which such individual would be entitled to have payment made under part A but for a denial or reduction of payments under section 1886(f)(2),

(H)(i) in the case of hospitals which provide services for which payment may be made under this title and in the case of critical access hospitals which provide critical access hospital services, to have all items and services (other than physicians' services as defined in regulations for purposes of section 1862(a)(14), and other than services described by section 1861(s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist) (I) that are furnished to an individual who is a patient of the hospital, and (II) for which the individual is entitled to have payment made under this title, furnished by the

hospital or otherwise under arrangements (as defined in section 1861(w)(1)) made by the hospital,

(ii) in the case of skilled nursing facilities which provide covered skilled nursing facility services—

(I) that are furnished to an individual who is a resident of the skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1861(s)(2)(D), that are furnished to such an individual without regard to such period), and

(II) for which the individual is entitled to have payment made under this title,

to have items and services (other than services described in section 1888(e)(2)(A)(ii)) furnished by the skilled nursing facility or otherwise under arrangements (as defined in section 1861(w)(1)) made by the skilled nursing facility,

(I) in the case of a hospital or critical access hospital—

(i) to adopt and enforce a policy to ensure compliance with the requirements of section 1867 and to meet the requirements of such section,

(ii) to maintain medical and other records related to individuals transferred to or from the hospital for a period of five years from the date of the transfer, and

(iii) to maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition,

(J) in the case of hospitals which provide inpatient hospital services for which payment may be made under this title, to be a participating provider of medical care under any health plan contracted for under section 1079 or 1086 of title 10, or under section 613 of title 38, United States Code, in accordance with admission practices, payment methodology, and amounts as prescribed under joint regulations issued by the Secretary and by the Secretaries of Defense and Transportation, in implementation of sections 1079 and 1086 of title 10, United States Code,

(K) not to charge any individual or any other person for items or services for which payment under this title is denied under section 1154(a)(2) by reason of a determination under section 1154(a)(1)(B),

(L) in the case of hospitals which provide inpatient hospital services for which payment may be made under this title, to be a participating provider of medical care under section 603 of title 38, United States Code, in accordance with such admission practices, and such payment methodology and amounts, as are prescribed under joint regulations issued by the Secretary and by the Secretary of Veterans Affairs in implementation of such section,

(M) in the case of hospitals, to provide to each individual who is entitled to benefits under part A (or to a person acting on the individual's behalf), at or about the time of the individual's admission as an inpatient to the hospital, a written statement (containing such language as the Secretary prescribes consistent with this paragraph) which explains—

- (i) the individual's rights to benefits for inpatient hospital services and for post-hospital services under this title,
 - (ii) the circumstances under which such an individual will and will not be liable for charges for continued stay in the hospital,
 - (iii) the individual's right to appeal denials of benefits for continued inpatient hospital services, including the practical steps to initiate such an appeal, and
 - (iv) the individual's liability for payment for services if such a denial of benefits is upheld on appeal,—and which provides such additional information as the Secretary may specify,
- (N) in the case of hospitals and critical access hospitals—
- (i) to make available to its patients the directory or directories of participating physicians (published under section 1842(h)(4)) for the area served by the hospital or critical access hospital,
 - (ii) if hospital personnel (including staff of any emergency or outpatient department) refer a patient to a non-participating physician for further medical care on an outpatient basis, the personnel must inform the patient that the physician is a nonparticipating physician and, whenever practicable, must identify at least one qualified participating physician who is listed in such a directory and from whom the patient may receive the necessary services,
 - (iii) to post conspicuously in any emergency department a sign (in a form specified by the Secretary) specifying rights of individuals under section 1867 with respect to examination and treatment for emergency medical conditions and women in labor, and
 - (iv) to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital participates in the medicaid program under a State plan approved under title XIX,
- (O) to accept as payment in full for services that are covered under this title and are furnished to any individual enrolled with a Medicare+Choice organization under part C, with a PACE provider under section 1894 or 1934, or with an eligible organization with a risk-sharing contract under section 1876, under section 1876(i)(2)(A) (as in effect before February 1, 1985), under section 402(a) of the Social Security Amendments of 1967, or under section 222(a) of the Social Security Amendments of 1972, which does not have a contract (or, in the case of a PACE provider, contract or other agreement) establishing payment amounts for services furnished to members of the organization or PACE program eligible individuals enrolled with the PACE provider, the amounts that would be made as a payment in full under this title (less any payments under sections 1886(d)(11) and 1886(h)(3)(D)) if the individuals were not so enrolled,
- (P) in the case of home health agencies which provide home health services to individuals entitled to benefits under this title who require catheters, catheter supplies, ostomy bags, and supplies related to ostomy care (described in section

1861(m)(5)), to offer to furnish such supplies to such an individual as part of their furnishing of home health services,

(Q) in the case of hospitals, skilled nursing facilities, home health agencies, and hospice programs, to comply with the requirement of subsection (f) (relating to maintaining written policies and procedures respecting advance directives),

(R) to contract only with a health care clearinghouse (as defined in section 1171) that meets each standard and implementation specification adopted or established under part C of title XI on or after the date on which the health care clearinghouse is required to comply with the standard or specification,

(S) in the case of a hospital that has a financial interest (as specified by the Secretary in regulations) in an entity to which individuals are referred as described in section 1861(ee)(2)(H)(ii), or in which such an entity has such a financial interest, or in which another entity has such a financial interest (directly or indirectly) with such hospital and such an entity, to maintain and disclose to the Secretary (in a form and manner specified by the Secretary) information on—

(i) the nature of such financial interest,

(ii) the number of individuals who were discharged from the hospital and who were identified as requiring home health services, and

(iii) the percentage of such individuals who received such services from such provider (or another such provider),

(T) in the case of hospitals and critical access hospitals, to furnish to the Secretary such data as the Secretary determines appropriate pursuant to subparagraph (E) of section 1886(d)(12) to carry out such section,

(U) in the case of hospitals which furnish inpatient hospital services for which payment may be made under this title, to be a participating provider of medical care both—

(i) under the contract health services program funded by the Indian Health Service and operated by the Indian Health Service, an Indian tribe, or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act), with respect to items and services that are covered under such program and furnished to an individual eligible for such items and services under such program; and

(ii) under any program funded by the Indian Health Service and operated by an urban Indian organization with respect to the purchase of items and services for an eligible urban Indian (as those terms are defined in such section 4),

in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodology, and rates of payment (including the acceptance of no more than such payment rate as payment in full for such items and services,

(V) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 (or a State occupational safety and health plan that is approved under 18(b) of such Act), to comply with the Bloodborne Pathogens stand-

ard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated), and

(W) in the case of a hospital described in section 1886(d)(1)(B)(v), to report quality data to the Secretary in accordance with subsection (k).

(W) maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider under this title, as specified by the Secretary.

In the case of a hospital which has an agreement in effect with an organization described in subparagraph (F), which organization's contract with the Secretary under part B of title XI is terminated on or after October 1, 1984, the hospital shall not be determined to be out of compliance with the requirement of such subparagraph during the six month period beginning on the date of the termination of that contract.

(2)(A) A provider of services may charge such individual or other person (i) the amount of any deduction or coinsurance amount imposed pursuant to section 1813(a)(1), (a)(3), or (a)(4), section 1833(b), or section 1861(y)(3) with respect to such items and services (not in excess of the amount customarily charged for such items and services by such provider), and (ii) an amount equal to 20 per centum of the reasonable charges for such items and services (not in excess of 20 per centum of the amount customarily charged for such items and services by such provider) for which payment is made under part B or which are durable medical equipment furnished as home health services (but in the case of items and services furnished to individuals with end-stage renal disease, an amount equal to 20 percent of the estimated amounts for such items and services calculated on the basis established by the Secretary). In the case of items and services described in section 1833(c), clause (ii) of the preceding sentence shall be applied by substituting for 20 percent the proportion which is appropriate under such section. A provider of services may not impose a charge under clause (ii) of the first sentence of this subparagraph with respect to items and services described in section 1861(s)(10)(A) and with respect to clinical diagnostic laboratory tests for which payment is made under part B. Notwithstanding the first sentence of this subparagraph, a home health agency may charge such an individual or person, with respect to covered items subject to payment under section 1834(a), the amount of any deduction imposed under section 1833(b) and 20 percent of the payment basis described in section 1834(a)(1)(B). In the case of items and services for which payment is made under part B under the prospective payment system established under section 1833(t), clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge, the applicable copayment amount established under section 1833(t)(5). In the case of services described in section 1833(a)(8) or section 1833(a)(9) for which payment is made under part B under section 1834(k), clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge for such services 20 percent of the lesser of the actual charge or

the applicable fee schedule amount (as defined in such section) for such services.

(B) Where a provider of services has furnished, at the request of such individual, items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under this title, such provider of services may also charge such individual or other person for such more expensive items or services to the extent that the amount customarily charged by it for the items or services furnished at such request exceeds the amount customarily charged by it for the items or services with respect to which payment may be made under this title.

(C) A provider of services may in accordance with its customary practice also appropriately charge any such individual for any whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished him with respect to which a deductible is imposed under section 1813(a)(2), except that (i) any excess of such charge over the cost to such provider for the blood (or equivalent quantities of packed red blood cells, as so defined) shall be deducted from any payment to such provider under this title, (ii) no such charge may be imposed for the cost of administration of such blood (or equivalent quantities of packed red blood cells, as so defined), and (iii) such charge may not be made to the extent such blood (or equivalent quantities of packed red blood cells, as so defined) has been replaced on behalf of such individual or arrangements have been made for its replacement on his behalf. For purposes of subparagraph (C), whole blood (or equivalent quantities of packed red blood cells, as so defined) furnished an individual shall be deemed replaced when the provider of services is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is imposed under section 1813(a)(2).

(D) Where a provider of services customarily furnishes items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under this title, such provider, notwithstanding the preceding provisions of this paragraph, may not, under the authority of section 1866(a)(2)(B)(ii), charge any individual or other person any amount for such items or services in excess of the amount of the payment which may otherwise be made for such items or services under this title if the admitting physician has a direct or indirect financial interest in such provider.

(3)(A) Under the agreement required under paragraph (1)(F)(ii), the quality improvement organization must perform functions (other than those covered under an agreement under paragraph (1)(F)(i)) under the third sentence of section 1154(a)(4)(A) and under section 1154(a)(14) with respect to services, furnished by the hospital, critical access hospital, facility, or agency involved, for which payment may be made under this title.

(B) For purposes of payment under this title, the cost of such an agreement to the hospital, critical access hospital, facility, or agency shall be considered a cost incurred by such hospital, critical access hospital, facility, or agency in providing covered services under this title and shall be paid directly by the Secretary to the quality improvement organization on behalf of such hospital, critical access

hospital, facility, or agency in accordance with a schedule established by the Secretary.

(C) Such payments—

(i) shall be transferred in appropriate proportions from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and

(ii) shall not be less in the aggregate for a fiscal year—

(I) in the case of hospitals, than the amount specified in paragraph (1)(F)(i)(III), and

(II) in the case of facilities, critical access hospitals, and agencies, than the amounts the Secretary determines to be sufficient to cover the costs of such organizations' conducting the activities described in subparagraph (A) with respect to such facilities, critical access hospitals, or agencies under part B of title XI.

(b)(1) A provider of services may terminate an agreement with the Secretary under this section at such time and upon such notice to the Secretary and the public as may be provided in regulations, except that notice of more than six months shall not be required.

(2) The Secretary may refuse to enter into an agreement under this section or, upon such reasonable notice to the provider and the public as may be specified in regulations, may refuse to renew or may terminate such an agreement after the Secretary—

(A) has determined that the provider fails to comply substantially with the provisions of the agreement, with the provisions of this title and regulations thereunder, or with a corrective action required under section 1886(f)(2)(B),

(B) has determined that the provider fails substantially to meet the applicable provisions of section 1861,

(C) has excluded the provider from participation in a program under this title pursuant to section 1128 or section 1128A, or

(D) has ascertained that the provider has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries.

(3) A termination of an agreement or a refusal to renew an agreement under this subsection shall become effective on the same date and in the same manner as an exclusion from participation under the programs under this title becomes effective under section 1128(c).

(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(V) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(U) by a hospital that is subject to the provisions of such Act.

(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

(c)(1) Where the Secretary has terminated or has refused to renew an agreement under this title with a provider of services, such provider may not file another agreement under this title unless the Secretary finds that the reason for the termination or nonrenewal has been removed and that there is reasonable assurance that it will not recur.

(2) Where the Secretary has terminated or has refused to renew an agreement under this title with a provider of services, the Secretary shall promptly notify each State agency which administers or supervises the administration of a State plan approved under title XIX of such termination or nonrenewal.

(d) If the Secretary finds that there is a substantial failure to make timely review in accordance with section 1861(k) of long-stay cases in a hospital, he may, in lieu of terminating his agreement with such hospital, decide that, with respect to any individual admitted to such hospital after a subsequent date specified by him, no payment shall be made under this title for inpatient hospital services (including inpatient psychiatric hospital services) after the 20th day of a continuous period of such services. Such decision may be made effective only after such notice to the hospital and to the public, as may be prescribed by regulations, and its effectiveness shall terminate when the Secretary finds that the reason therefor has been removed and that there is reasonable assurance that it will not recur. The Secretary shall not make any such decision except after reasonable notice and opportunity for hearing to the institution or agency affected thereby.

(e) For purposes of this section, the term "provider of services" shall include—

(1) a clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1861(p)(4)(A) (or meets the requirements of such section through the operation of subsection (g) or (l)(2) of section 1861), or if, in the case of a public health agency, such agency meets the requirements of section 1861(p)(4)(B) (or meets the requirements of such section through the operation of subsection (g) or (l)(2) of section 1861), but only with respect to the furnishing of outpatient physical therapy services (as therein defined), (through the operation of section 1861(g)) with respect to the furnishing of outpatient occupational therapy services, or (through the operation of section 1861(l)(2)) with respect to the furnishing of outpatient speech-language pathology; and

(2) a community mental health center (as defined in section 1861(ff)(3)(B)), but only with respect to the furnishing of partial hospitalization services (as described in section 1861(ff)(1)).

(f)(1) For purposes of subsection (a)(1)(Q) and sections 1819(c)(2)(E), 1833(s), 1855(i), 1876(c)(8), and 1891(a)(6), the requirement of this subsection is that a provider of services, Medicare+Choice organization, or prepaid or eligible organization (as the case may be) maintain written policies and procedures with

respect to all adult individuals receiving medical care by or through the provider or organization—

(A) to provide written information to each such individual concerning—

(i) an individual's rights under State law (whether statutory or as 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 advance directives (as defined in paragraph (3)), and

(ii) the written policies of the provider or organization respecting the implementation of such rights;

(B) to document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive;

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

(D) to ensure compliance with requirements of State law (whether statutory or as recognized by the courts of the State) respecting advance directives at facilities of the provider or organization; and

(E) to provide (individually or with others) for education for staff and the community on issues concerning advance directives.

Subparagraph (C) shall not be construed as requiring the provision of care which conflicts with an advance directive.

(2) The written information described in paragraph (1)(A) shall be provided to an adult individual—

(A) in the case of a hospital, at the time of the individual's admission as an inpatient,

(B) in the case of a skilled nursing facility, at the time of the individual's admission as a resident,

(C) in the case of a home health agency, in advance of the individual coming under the care of the agency,

(D) in the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program, and

(E) in the case of an eligible organization (as defined in section 1876(b)) or an organization provided payments under section 1833(a)(1)(A) or a Medicare+Choice organization, at the time of enrollment of the individual with the organization.

(3) In this subsection, the term "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) and relating to the provision of such care when the individual is incapacitated.

(4) For construction relating to this subsection, see section 7 of the Assisted Suicide Funding Restriction Act of 1997 (relating to clarification respecting assisted suicide, euthanasia, and mercy killing).

(g) Except as permitted under subsection (a)(2), any person who knowingly and willfully presents, or causes to be presented, a bill or request for payment inconsistent with an arrangement under subsection (a)(1)(H) or in violation of the requirement for such an arrangement, is subject to a civil money penalty of not to exceed

\$2,000. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(h)(1)(A) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or with a determination described in subsection (b)(2) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g), except that, in so applying such sections and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.

(C)(i) The Secretary shall develop and implement a process to expedite proceedings under this subsection in which—

(I) the remedy of termination of participation has been imposed;

(II) a remedy described in clause (i) or (iii) of section 1819(h)(2)(B) has been imposed, but only if such remedy has been imposed on an immediate basis; or

(III) a determination has been made as to a finding of substandard quality of care that results in the loss of approval of a skilled nursing facility's nurse aide training program.

(ii) Under such process under clause (i), priority shall be provided in cases of termination described in clause (i)(I).

(iii) Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.

(2) An institution or agency is not entitled to separate notice and opportunity for a hearing under both section 1128 and this section with respect to a determination or determinations based on the same underlying facts and issues.

(i)(1) If the Secretary determines that a psychiatric hospital which has an agreement in effect under this section no longer meets the requirements for a psychiatric hospital under this title and further finds that the hospital's deficiencies—

(A) immediately jeopardize the health and safety of its patients, the Secretary shall terminate such agreement; or

(B) do not immediately jeopardize the health and safety of its patients, the Secretary may terminate such agreement, or provide that no payment will be made under this title with respect

to any individual admitted to such hospital after the effective date of the finding, or both.

(2) If a psychiatric hospital, found to have deficiencies described in paragraph (1)(B), has not complied with the requirements of this title—

(A) within 3 months after the date the hospital is found to be out of compliance with such requirements, the Secretary shall provide that no payment will be made under this title with respect to any individual admitted to such hospital after the end of such 3-month period, or

(B) within 6 months after the date the hospital is found to be out of compliance with such requirements, no payment may be made under this title with respect to any individual in the hospital until the Secretary finds that the hospital is in compliance with the requirements of this title.

(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) ENROLLMENT PROCESS.—

(A) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title. Such process shall include screening of providers and suppliers in accordance with paragraph (2), a provisional period of enhanced oversight in accordance with paragraph (3), disclosure requirements in accordance with paragraph (4), the imposition of temporary enrollment moratoria in accordance with paragraph (5), and the establishment of compliance programs in accordance with paragraph (6).

(B) DEADLINES.—The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under this subparagraph.

(C) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this title.

(2) PROVIDER SCREENING.—

(A) PROCEDURES.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish procedures under which screening is conducted with respect to providers of medical or other items or services and suppliers under the program under this title, the Medicaid program under title XIX, and the CHIP program under title XXI.

(B) LEVEL OF SCREENING.—The Secretary shall determine the level of screening conducted under this paragraph according to the risk of fraud, waste, and abuse, as determined by the Secretary, with respect to the category of provider of medical or other items or services or supplier. Such screening—

(i) shall include a licensure check, which may include such checks across States; and

(ii) may, as the Secretary determines appropriate based on the risk of fraud, waste, and abuse described in the preceding sentence, include—

(I) a criminal background check;

(II) fingerprinting;

(III) unscheduled and unannounced site visits, including preenrollment site visits;

(IV) database checks (including such checks across States); and

(V) such other screening as the Secretary determines appropriate.

(C) APPLICATION FEES.—

(i) INSTITUTIONAL PROVIDERS.—Except as provided in clause (ii), the Secretary shall impose a fee on each institutional provider of medical or other items or services or supplier (such as a hospital or skilled nursing facility) with respect to which screening is conducted under this paragraph in an amount equal to—

(I) for 2010, \$500; and

(II) for 2011 and each subsequent year, the amount determined under this clause for the preceding year, adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year.

(ii) HARDSHIP EXCEPTION; WAIVER FOR CERTAIN MEDICAID PROVIDERS.—The Secretary may, on a case-by-case basis, exempt a provider of medical or other items or services or supplier from the imposition of an application fee under this subparagraph if the Secretary determines that the imposition of the application fee would result in a hardship. The Secretary may waive the application fee under this subparagraph for providers enrolled in a State Medicaid program for whom the State demonstrates that imposition of the fee would impede beneficiary access to care.

(iii) USE OF FUNDS.—Amounts collected as a result of the imposition of a fee under this subparagraph shall be used by the Secretary for program integrity efforts, including to cover the costs of conducting screening under this paragraph and to carry out this subsection and section 1128J.

(D) APPLICATION AND ENFORCEMENT.—

(i) NEW PROVIDERS OF SERVICES AND SUPPLIERS.—The screening under this paragraph shall apply, in the case of a provider of medical or other items or services or supplier who is not enrolled in the program under this title, title XIX, or title XXI as of the date of enactment of this paragraph, on or after the date that is 1 year after such date of enactment.

(ii) CURRENT PROVIDERS OF SERVICES AND SUPPLIERS.—The screening under this paragraph shall

apply, in the case of a provider of medical or other items or services or supplier who is enrolled in the program under this title, title XIX, or title XXI as of such date of enactment, on or after the date that is 2 years after such date of enactment.

(iii) REVALIDATION OF ENROLLMENT.—Effective beginning on the date that is 180 days after such date of enactment, the screening under this paragraph shall apply with respect to the revalidation of enrollment of a provider of medical or other items or services or supplier in the program under this title, title XIX, or title XXI.

(iv) LIMITATION ON ENROLLMENT AND REVALIDATION OF ENROLLMENT.—In no case may a provider of medical or other items or services or supplier who has not been screened under this paragraph be initially enrolled or reenrolled in the program under this title, title XIX, or title XXI on or after the date that is 3 years after such date of enactment.

(E) USE OF INFORMATION FROM THE DEPARTMENT OF TREASURY CONCERNING TAX DEBTS.—In reviewing the application of a provider of services or supplier to enroll or reenroll under the program under this title, the Secretary shall take into account the information supplied by the Secretary of the Treasury pursuant to section 6103(1)(22) of the Internal Revenue Code of 1986, in determining whether to deny such application or to apply enhanced oversight to such provider of services or supplier pursuant to paragraph (3) if the Secretary determines such provider of services or supplier owes such a debt.

(F) EXPEDITED RULEMAKING.—The Secretary may promulgate an interim final rule to carry out this paragraph.

(3) PROVISIONAL PERIOD OF ENHANCED OVERSIGHT FOR NEW PROVIDERS OF SERVICES AND SUPPLIERS.—

(A) IN GENERAL.—The Secretary shall establish procedures to provide for a provisional period of not less than 30 days and not more than 1 year during which new providers of medical or other items or services and suppliers, as the Secretary determines appropriate, including categories of providers or suppliers, would be subject to enhanced oversight, such as prepayment review and payment caps, under the program under this title, the Medicaid program under title XIX, and the CHIP program under title XXI.

(B) IMPLEMENTATION.—The Secretary may establish by program instruction or otherwise the procedures under this paragraph.

(4) 90-DAY PERIOD OF ENHANCED OVERSIGHT FOR INITIAL CLAIMS OF DME SUPPLIERS.—For periods beginning after January 1, 2011, if the Secretary determines that there is a significant risk of fraudulent activity among suppliers of durable medical equipment, in the case of a supplier of durable medical equipment who is within a category or geographic area under title XVIII identified pursuant to such determination and who is initially enrolling under such title, the Secretary shall, not-

withstanding sections 1816(c), 1842(c), and 1869(a)(2), withhold payment under such title with respect to durable medical equipment furnished by such supplier during the 90-day period beginning on the date of the first submission of a claim under such title for durable medical equipment furnished by such supplier.

(5) INCREASED DISCLOSURE REQUIREMENTS.—

(A) DISCLOSURE.—A provider of medical or other items or services or supplier who submits an application for enrollment or revalidation of enrollment in the program under this title, title XIX, or title XXI on or after the date that is 1 year after the date of enactment of this paragraph shall disclose (in a form and manner and at such time as determined by the Secretary) any current or previous affiliation (directly or indirectly) with a provider of medical or other items or services or supplier that has uncollected debt, has been or is subject to a payment suspension under a Federal health care program (as defined in section 1128B(f)), has been excluded from participation under the program under this title, the Medicaid program under title XIX, or the CHIP program under title XXI, or has had its billing privileges denied or revoked.

(B) AUTHORITY TO DENY ENROLLMENT.—If the Secretary determines that such previous affiliation poses an undue risk of fraud, waste, or abuse, the Secretary may deny such application. Such a denial shall be subject to appeal in accordance with paragraph (7).

(6) AUTHORITY TO ADJUST PAYMENTS OF PROVIDERS OF SERVICES AND SUPPLIERS WITH THE SAME TAX IDENTIFICATION NUMBER FOR MEDICARE OBLIGATIONS.—

(A) IN GENERAL.—Notwithstanding any other provision of this title, in the case of an applicable provider of services or supplier, the Secretary may make any necessary adjustments to payments to the applicable provider of services or supplier under the program under this title in order to satisfy any amount described in subparagraph (B)(ii) due from such obligated provider of services or supplier.

(B) DEFINITIONS.—In this paragraph:

(i) IN GENERAL.—The term “applicable provider of services or supplier” means a provider of services or supplier that has the same taxpayer identification number assigned under section 6109 of the Internal Revenue Code of 1986 as is assigned to the obligated provider of services or supplier under such section, regardless of whether the applicable provider of services or supplier is assigned a different billing number or national provider identification number under the program under this title than is assigned to the obligated provider of services or supplier.

(ii) OBLIGATED PROVIDER OF SERVICES OR SUPPLIER.—The term “obligated provider of services or supplier” means a provider of services or supplier that owes an amount that is more than the amount re-

quired to be paid under the program under this title (as determined by the Secretary).

(7) TEMPORARY MORATORIUM ON ENROLLMENT OF NEW PROVIDERS.—

(A) IN GENERAL.—The Secretary may impose a temporary moratorium on the enrollment of new providers of services and suppliers, including categories of providers of services and suppliers, in the program under this title, under the Medicaid program under title XIX, or under the CHIP program under title XXI if the Secretary determines such moratorium is necessary to prevent or combat fraud, waste, or abuse under either such program.

(B) LIMITATION ON REVIEW.—There shall be no judicial review under section 1869, section 1878, or otherwise, of a temporary moratorium imposed under subparagraph (A).

(8) COMPLIANCE PROGRAMS.—

(A) IN GENERAL.—On or after the date of implementation determined by the Secretary under subparagraph (C), a provider of medical or other items or services or supplier within a particular industry sector or category shall, as a condition of enrollment in the program under this title, title XIX, or title XXI, establish a compliance program that contains the core elements established under subparagraph (B) with respect to that provider or supplier and industry or category.

(B) ESTABLISHMENT OF CORE ELEMENTS.—The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish core elements for a compliance program under subparagraph (A) for providers or suppliers within a particular industry or category.

(C) TIMELINE FOR IMPLEMENTATION.—The Secretary shall determine the timeline for the establishment of the core elements under subparagraph (B) and the date of the implementation of subparagraph (A) for providers or suppliers within a particular industry or category. The Secretary shall, in determining such date of implementation, consider the extent to which the adoption of compliance programs by a provider of medical or other items or services or supplier is widespread in a particular industry sector or with respect to a particular provider or supplier category.

(8) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.

(k) QUALITY REPORTING BY CANCER HOSPITALS.—

(1) IN GENERAL.—For purposes of fiscal year 2014 and each subsequent fiscal year, a hospital described in section 1886(d)(1)(B)(v) shall submit data to the Secretary in accordance with paragraph (2) with respect to such a fiscal year.

(2) SUBMISSION OF QUALITY DATA.—For fiscal year 2014 and each subsequent fiscal year, each hospital described in such section shall submit to the Secretary data on quality measures specified under paragraph (3). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(3) QUALITY MEASURES.—

(A) IN GENERAL.—Subject to subparagraph (B), any measure specified by the Secretary under this paragraph must have been endorsed by the entity with a contract under section 1890(a).

(B) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(C) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this paragraph that will be applicable with respect to fiscal year 2014.

(4) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under paragraph (4) available to the public. Such procedures shall ensure that a hospital described in section 1886(d)(1)(B)(v) has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

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