

Social Security Act Title XVIII: Health Insurance for the Aged and Disabled (Medicare)

Enacted in 1965, Title XVIII of the Social Security Act¹ established regulations for the Medicare program, which guarantees access to health insurance for all Americans, aged 65 and older, younger people with specific disabilities, and individuals with end stage renal disease. Title XVIII includes provisions regarding the collection, disclosure, and use of Medicare beneficiaries' health information. The Medicare program has four parts: Part A, Part B, Part C, and Part D.

The Medicare program is administered by the Centers for Medicare and Medicaid Services (CMS), which is a government agency within the U.S. Department of Health and Human Services (HHS).

Part A- Hospital Insurance Benefits for the Aged and Disabled

Medicare Part A provides coverage for hospital, post-hospital, home-health, and hospice care.² For most Americans, there are no premiums for Part A since it is paid for out of their payroll taxes.³

Part B – Supplementary Medical Insurance Benefits for the Aged and Disabled

Medicare Part B is a voluntary insurance program that provides medical insurance benefits to the aged and disabled. The program is financed by premium contributions by enrollees and federal government funds.⁴

General Record-Keeping Requirements

The following providers must maintain central clinical records on all patients:

- Hospice programs;⁵
- Home health agencies;⁶
- Clinics and rehabilitation agencies providing outpatient physical therapy services;⁷
- Rural health clinics must maintain clinical records on all patients;⁸
- Comprehensive outpatient rehabilitation facilities;⁹
- Hospitals;¹⁰

¹ Social Security Act, Volume II, Title 18, codified at 42 U.S.C. §§1395-1395cc

² Social Security Act §1811, 42 U.S.C. 1395c.

³ Medicare Program - General Information, *Centers for Medicare and Medicaid Services* (available at: <http://cms.gov/Medicare/Medicare-General-Information/MedicareGenInfo/index.html>).

⁴ Social Security Act §1831, 42 U.S.C. 1395j.

⁵ Social Security Act § 1861(dd)(2)(C), 42 U.S.C. 1395x(dd)(2)(C).

⁶ Social Security Act § 1861(o)(3), 42 U.S.C. 1395x(o)(3).

⁷ Social Security Act § 1861(p)(4)(A)(iii), 42 U.S.C. 1395x(p)(4)(A)(iii).

⁸ Social Security Act § 1861(aa)(2)(C), 42 U.S.C. 1395x(aa)(2)(C).

⁹ Social Security Act § 1861(cc)(2)(G), 42 U.S.C. 1395x(cc)(2)(G).

¹⁰ Social Security Act § 1861(e)(2), 42 U.S.C. 1395x(e)(2).

- Psychiatric hospitals;¹¹ and
- SNFs.¹²

In addition, every individual and organization providing services to Medicare beneficiaries must document in the individual's medical record whether or not the individual has executed an advance directive.¹³

*Hospitals*¹⁴

Providers¹⁵ of inpatient hospital services must certify the beneficiary's need for such services¹⁶ and must periodically provide materials for recertification in accordance with regulations.¹⁷

Hospitals,¹⁸ including psychiatric hospitals,¹⁹ must implement the following:

- A utilization review plan²⁰ that includes the following:
 - Review of admissions to the institution;
 - Review of the duration of stays in the institution;
 - Review of the medical necessity of the professional service furnished;²¹ and
 - Provision for prompt notification to the institution, the individual and his attending physician of a finding that further stay in the institution is not medically necessary.²²
- A discharge planning process²³ that includes:
 - Early identification of patients likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning;²⁴

¹¹ Social Security Act § 1861(f)(3), 42 U.S.C. 1395x(f)(3).

¹² Social Security Act § 1819(b)(6)(C), 42 U.S.C. 1395i-3(b)(6)(C).

¹³ Social Security Act § 1866(f)(1)(B), 42 U.S.C. 1395cc(f)(1)(B).

¹⁴ Social Security Act § 1814, 42 U.S.C. 1395f ; Social Security Act § 1833, 42 U.S.C. 1395l; Social Security Act § 1861, 42 U.S.C. 1395x; Social Security Act § 1866, 42 U.S.C. 1395cc; Social Security Act § 1867, 42 U.S.C. 1395dd; Social Security Act § 1886, 42 U.S.C. 1395ww.

¹⁵ Provider = a physician, or for (B) services, a physician, an NP, a clinical nurse specialist or a PA who does not have a direct/indirect employment relationship with the facility but is working in collaboration with a physician.

¹⁶ Social Security Act § 1814(a)(3), 42 U.S.C. 1395f(a)(3) (inpatient hospital services); Social Security Act § 1814(a)(2)(A), 42 U.S.C. 1395f(a)(2)(A) (inpatient psychiatric hospital services); Social Security Act § 1814(a)(2)(D), 42 U.S.C. 1395f(a)(2)(D) (inpatient hospital services provided in connection with a dental procedure).

¹⁷ Social Security Act § 1814(a), 42 U.S.C. 1395f(a).

¹⁸ Social Security Act § 1861(e), 42 U.S.C. 1395x.

¹⁹ Social Security Act § 1861(f), 42 U.S.C. 1395x(f).

²⁰ Social Security Act § 1861(e)(6)(A), 42 U.S.C. 1395x(e)(6)(A).

²¹ Social Security Act § 1861(k)(1)(A), 42 U.S.C. 1395x(k)(1)(A).

²² Social Security Act § 1861(k)(4), 42 U.S.C. 1395x(k)(4).

²³ Social Security Act § 1861(e)(6)(B), 42 U.S.C. 1395x(e)(6)(B).

²⁴ Social Security Act § 1861(ee)(2)(A), 42 U.S.C. 1395x(ee)(2)(A).

- Discharge planning evaluations for such patients and for other patients upon request;²⁵
- Evaluation of a patient's likely need for appropriate post-hospital services;²⁶
- Inclusion of the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan; and
- Provision for the discussion of the results of the evaluation with the patient or his representative.²⁷

Long-term care hospitals must have a patient review process that:

- Is documented in the patient's medical record
- Screens patients prior to admission for appropriateness of admission
- Validates within 48 hours of admission that patient meets admission criteria,
- Regularly evaluates patients throughout their stay for continuation of care, and
- Assesses the available discharge options when patients no longer meet such continued stay criteria.²⁸

Long-term care hospitals must have an interdisciplinary team of health professionals, including physicians, prepare individualized treatment plans for each patient.²⁹

All hospitals, including critical access hospitals must adopt and enforce a policy to ensure compliance with § 1867³⁰ and must maintain medical and other records related to individuals transferred to or from the hospital for a period of five years after the date of transfer.³¹

If, after being informed of the risks and benefits by the hospital, an individual refuses to consent to examination and treatment or to transfer to another medical facility, the hospital shall take all reasonable steps to secure the individual's written consent to refuse examination, treatment³² or transfer.³³ If an individual at a hospital has an emergency medical condition that has not been stabilized, the hospital may not transfer the individual unless, after being informed of the risk of the transfer, the individual in writing requests transfer³⁴ and a physician has signed a certification that based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual, and in the case of labor, to the unborn child from effecting the transfer.³⁵ An appropriate transfer is one in which the transferring hospital

²⁵ Social Security Act § 1861(ee)(2)(B), 42 U.S.C. 1395x(ee)(2)(B).

²⁶ Social Security Act § 1861(ee)(2)(D), 42 U.S.C. 1395x(ee)(2)(D).

²⁷ Social Security Act § 1861(ee)(2)(E), 42 U.S.C. 1395x(ee)(2)(E).

²⁸ Social Security Act § 1861(ccc)(4)(A), 42 U.S.C. 1395x(ccc)(4)(A).

²⁹ Social Security Act § 1861(ccc)(4)(C), 42 U.S.C. 1395x(ccc)(4)(C).

³⁰ Social Security Act § 1866(a)(1)(F)(ii)(I)(i), 42 U.S.C. 1395cc(a)(1)(F)(ii)(I)(i).

³¹ Social Security Act § 1866(a)(1)(F)(ii)(I)(ii), 42 U.S.C. 1395cc(a)(1)(F)(ii)(I)(ii).

³² Social Security Act § 1867(b)(2), 42 U.S.C. 1395dd(b)(2).

³³ Social Security Act § 1867(b)(3), 42 U.S.C. 1395dd(b)(3).

³⁴ Social Security Act § 1867(c)(1)(A)(i), 42 U.S.C. 1395dd(c)(1)(A)(i).

³⁵ Social Security Act § 1867(c)(1)(A)(ii), 42 U.S.C. 1395dd(c)(1)(A)(ii).

sends to the receiving facility all medical records, or copies thereof available at the time of transfer, related to the emergency condition for which the individual has presented, including records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, treatment provided, and the results of any tests.³⁶

In considering allegations of violations of the requirements of this section, the Secretary³⁷ will request the appropriate utilization and quality control peer review organization to assess whether the individual involved had an emergency medical condition which had not been stabilized, and provide a report on its findings.³⁸ The Secretary will provide a copy of the organization's report to the hospital or physician consistent with confidentiality requirements imposed on the organization.³⁹

Payment to Hospitals for Inpatient Hospital Services⁴⁰

An eligible hospital will be treated as a meaningful EHR user, and thus eligible for increased payments,⁴¹ if the hospital demonstrates that during an EHR reporting period for a payment year, the hospital is using certified EHR technology in a meaningful manner,⁴² that such certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination,⁴³ and, using certified EHR technology, the hospital submits information for such period on such clinical quality measures as selected by the Secretary.⁴⁴ The Secretary will post on CMS' website a list of the names of the eligible hospitals that are meaningful EHR users after ensuring that an eligible hospital has the opportunity to review the data.⁴⁵

The Secretary will establish a value-based purchasing program under which incentive payments are made to hospitals that meet performance standards established by the Secretary⁴⁶ with respect to the quality measures selected by the Secretary⁴⁷ for inpatient hospital settings other than readmissions,⁴⁸ which will include levels of achievement and improvement.⁴⁹ Under this program, the Secretary will make available to the public the information regarding performance under the Program,⁵⁰ including the performance of

³⁶ Social Security Act § 1867(c)(2), 42 U.S.C. 1395dd(c)(2).

³⁷ "Secretary" as used throughout the document refers to the Secretary of the U.S. Department of Health and Human Services.

³⁸ Social Security Act § 1867(d)(3), 42 U.S.C. 1395dd(d)(3) .

³⁹ Social Security Act § 1867(d)(3), 42 U.S.C. 1395dd(d)(3) .

⁴⁰ Social Security Act § 1886, 42 U.S.C. 1395ww.

⁴¹ Social Security Act § 1886(n)(1), 42 U.S.C. 1395ww(n)(1).

⁴² Social Security Act § 1886(n)(3)(A)(i), 42 U.S.C. 1395ww(n)(3)(A)(i).

⁴³ Social Security Act § 1886(n)(3)(A)(ii), 42 U.S.C. 1395ww(n)(3)(A)(ii).

⁴⁴ Social Security Act § 1886(n)(3)(A)(iii), 42 U.S.C. 1395ww(n)(3)(A)(iii).

⁴⁵ Social Security Act § 1886(n)(4)(B), 42 U.S.C. 1395ww(n)(4)(B).

⁴⁶ Social Security Act § 1886(o)(1)(A), 42 U.S.C. 1395ww(o)(1)(A).

⁴⁷ Social Security Act § 1886(o)(3)(A), 42 U.S.C. 1395ww(o)(3)(A).

⁴⁸ Social Security Act § 1886(o)(2)(A), 42 U.S.C. 1395ww(o)(2)(A).

⁴⁹ Social Security Act § 1886(o)(3)(B), 42 U.S.C. 1395ww(o)(3)(B).

⁵⁰ Social Security Act § 1886(o)(10)(A)(i), 42 U.S.C. 1395ww(o)(10)(A)(i).

the hospital with respect to each measure that applies to the hospital;⁵¹ the performance of the hospital with respect to each condition or procedure;⁵² and the hospital performance score assessing the total performance of the hospital.⁵³ Such information will be posted on the Hospital Compare website.⁵⁴

In order to provide an incentive to applicable hospitals⁵⁵ to reduce hospital acquired conditions,⁵⁶ the Secretary will adjust payments to hospitals.⁵⁷ The Secretary will annually provide confidential reports to applicable hospitals with respect to hospital acquired conditions of the applicable hospital.⁵⁸ The Secretary will make information available to the public regarding hospital acquired conditions of each applicable hospital,⁵⁹ and will post such information on the Hospital Compare website.⁶⁰

In operating the hospital readmissions reduction program, the Secretary will make information available to the public regarding readmission rates of each hospital in the program,⁶¹ and will post such information on the Hospital Compare website.⁶² The Secretary will calculate readmission rates for all patients for hospitals for an applicable condition⁶³ and will post such information on the Hospital Compare website.⁶⁴ Each specified hospital will submit to the Secretary, data and information necessary to calculate all patient readmission rates.⁶⁵

Physician Services

Payment for Physician's Services⁶⁶

The Secretary will monitor changes in the utilization of and access to services furnished under Part B within geographic, population and service-related categories,⁶⁷ as well as possible sources of inappropriate utilization of services.⁶⁸ The Secretary will annually report to Congress on changes in the utilization of services, and will include an

⁵¹ Social Security Act § 1886(o)(10)(A)(i)(I), 42 U.S.C. 1395ww(o)(10)(A)(i)(I).

⁵² Social Security Act § 1886(o)(10)(A)(i)(II), 42 U.S.C. 1395ww(o)(10)(A)(i)(II).

⁵³ Social Security Act § 1886(o)(10)(A)(i)(III), 42 U.S.C. 1395ww(o)(10)(A)(i)(III).

⁵⁴ Social Security Act § 1886(o)(10)(A)(iii), 42 U.S.C. 1395ww(o)(10)(A)(iii).

⁵⁵ Definition of applicable hospital. Social Security Act § 1886(p)(2), 42 U.S.C. 1395ww(p)(2).

⁵⁶ "Hospital acquired condition" is defined in Social Security Act § 1886(p)(3), 42 U.S.C. 1395ww(p)(3).

⁵⁷ Social Security Act § 1886(p)(1), 42 U.S.C. 1395ww(p)(1).

⁵⁸ Social Security Act § 1886(p)(5), 42 U.S.C. 1395ww(p)(5).

⁵⁹ Social Security Act § 1886(p)(6)(A), 42 U.S.C. 1395ww(p)(6)(A).

⁶⁰ Social Security Act § 1886(p)(6)(C), 42 U.S.C. 1395ww(p)(6)(C).

⁶¹ Social Security Act § 1886(q)(6)(A), 42 U.S.C. 1395ww(q)(6)(A).

⁶² Social Security Act § 1886(q)(6)(C), 42 U.S.C. 1395ww(q)(6)(C).

⁶³ Social Security Act § 1886(q)(8)(A), 42 U.S.C. 1395ww(q)(8)(A).

⁶⁴ Social Security Act § 1886(q)(8)(B), 42 U.S.C. 1395ww(q)(8)(B).

⁶⁵ Social Security Act § 1886(q)(8)(C)(i), 42 U.S.C. 1395ww(q)(8)(C)(i).

⁶⁶ Social Security Act § 1848, 42 U.S.C. 1395w-4.

⁶⁷ Social Security Act § 1848(g)(7)(A)(i), 42 U.S.C. 1395w-4(g)(7)(A)(i).

⁶⁸ Social Security Act § 1848(g)(7)(A)(ii), 42 U.S.C. 1395w-4(g)(7)(A)(ii).

examination of the factors which may contribute to such changes,⁶⁹ as well as recommendations addressing any identified patterns of inappropriate utilization.⁷⁰

The Secretary will establish a Physician Feedback Program under which the Secretary will use claims data to provide confidential reports to physicians that measure the resources involved in furnishing care to individuals; the Secretary may include information on the quality of care furnished to individuals by the physician in such reports.⁷¹ The Secretary will provide reports to physicians that compare patterns of resource use of the individual physician to such patterns of other physicians;⁷² in preparing such reports, the Secretary will make appropriate adjustments to account for differences in socioeconomic and demographic characteristics, ethnicity, and health status of individuals.⁷³

The Secretary will provide incentive payments to eligible professionals for the adoption and meaningful use of EHR technology.⁷⁴ An eligible professional will be treated as a meaningful EHR user if the professional demonstrates that such EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination,⁷⁵ and if the professional submits information using such EHR technology on clinical quality measures.⁷⁶ The Secretary will post on CMS' website a list of the eligible professionals who are meaningful EHR users.⁷⁷

The Secretary will implement a reporting system for eligible professionals⁷⁸ of data on consensus-based quality measures⁷⁹ and provide incentive payments for professionals engaging in quality reporting.⁸⁰ The Secretary will also provide incentive payments to professionals who engage in electronic prescribing.⁸¹ The Secretary will post on CMS' website a list of the names of the eligible professionals who satisfactorily submitted data on quality measures,⁸² as well as a list of those eligible professionals who are successful electronic prescribers.⁸³

⁶⁹ Social Security Act § 1848(g)(7)(B), 42 U.S.C. 1395w-4(g)(7)(B).

⁷⁰ Social Security Act § 1848(g)(7)(c)(i), 42 U.S.C. 1395w-4(g)(7)(c)(i).

⁷¹ Social Security Act § 1848(n)(1)(A), 42 U.S.C. 1395w-4(n)(1)(A).

⁷² Social Security Act § 1848(n)(9)(B), 42 U.S.C. 1395w-4(n)(9)(B).

⁷³ Social Security Act § 1848(n)(9)(D)(i), 42 U.S.C. 1395w-4(n)(9)(D)(i).

⁷⁴ Social Security Act § 1848(o)(1)(A), 42 U.S.C. 1395w-4(o)(1)(A).

⁷⁵ Social Security Act § 1848(o)(2)(A)(ii), 42 U.S.C. 1395w-4(o)(2)(A)(ii).

⁷⁶ Social Security Act § 1848(o)(2)(A)(iii), 42 U.S.C. 1395w-4(o)(2)(A)(iii).

⁷⁷ Social Security Act § 1848(o)(2)(D), 42 U.S.C. 1395w-4(o)(2)(D).

⁷⁸ Definition of eligible professional. Social Security Act § 1848(k)(3)(B), 42 U.S.C. 1395w-4(k)(3)(B).

⁷⁹ Social Security Act § 1848(k)(1), 42 U.S.C. 1395w-4(k)(1).

⁸⁰ Social Security Act § 1848(m)(1)(A), 42 U.S.C. 1395w-4(m)(1)(A).

⁸¹ Social Security Act § 1848(m), 42 U.S.C. 1395w-4(m).

⁸² Social Security Act § 1848(m)(5)(G)(i), 42 U.S.C. 1395w-4(m)(5)(G)(i).

⁸³ Social Security Act § 1848(m)(5)(G)(ii), 42 U.S.C. 1395w-4(m)(5)(G)(ii) (*See* Social Security Act § 1848(m)(3)(B) for standards on a successful electronic prescriber).

The Secretary will develop a plan by January 1, 2012 to integrate reporting on quality measures with reporting requirements relating to the meaningful use of electronic health records.⁸⁴ This integration will include the selection of measures, the reporting of which would demonstrate meaningful use of an electronic health record⁸⁵ and quality of care furnished to an individual.⁸⁶

The Secretary will establish a payment modifier that provides for differential payment to a physician based upon the quality of care furnished compared to cost.⁸⁷ Quality of care will be evaluated based on a composite of measures of the quality of care furnished, as established by the Secretary, such as measures that reflect health outcomes.⁸⁸

Public Reporting of Performance Information⁸⁹

CMS must implement a plan for making publicly available, physician performance information, including information available under the Physician Quality Reporting System by January 1, 2011.⁹⁰ The Secretary must, by January 1, 2013, implement a plan to make available on the Physician Compare website, comparable information on the quality and patient experience of Medicare participating providers.⁹¹ The reported information must include measures collected under the Physician Quality Reporting System, an assessment of patient outcomes, assessment of care coordination and care transitions, an assessment of efficiency, an assessment of patient experience, and measures related to patient safety.⁹² The Secretary must also ensure that all information related to physician performance and patient experience protects the privacy and confidentiality of individually identifiable health information.⁹³

Skilled Nursing Facilities

Conditions of and Limitations on Payment for Services⁹⁴

Payments for furnished inpatient services may only be made to eligible providers (under Social Security Act §1866) if a provider⁹⁵ certifies, as appropriate,⁹⁶ the beneficiary's need for post-hospital extended care services in a skilled nursing facility.⁹⁷ Providers

⁸⁴ Social Security Act § 1848(m)(7), 42 U.S.C. 1395w-4(m)(7).

⁸⁵ Social Security Act § 1848(m)(7)(A)(i), 42 U.S.C. 1395w-4(m)(7)(A)(i).

⁸⁶ Social Security Act § 1848(m)(7)(A)(ii), 42 U.S.C. 1395w-4(m)(7)(A)(ii).

⁸⁷ Social Security Act § 1848(p)(1), 42 U.S.C. 1395w-4(p)(1).

⁸⁸ Social Security Act § 1848(p)(2)(B)(i), 42 U.S.C. 1395w-4(p)(2)(B)(i).

⁸⁹ 42 U.S.C. §1395w-5.

⁹⁰ 42 U.S.C. §1395w-5(a)(1).

⁹¹ 42 U.S.C. §1395w-5(a)(2).

⁹² 42 U.S.C. §1395w-5(a)(2).

⁹³ 42 U.S.C. §1395w-5(c).

⁹⁴ Social Security Act §1814, 42 U.S.C. 1395f.

⁹⁵ Provider = a physician, or for (B) services, a physician, an NP, a clinical nurse specialist or a PA who does not have a direct/indirect employment relationship with the facility but is working in collaboration with a physician

⁹⁶ Social Security Act § 1814(a), 42 U.S.C. 1395f(a).

⁹⁷ Social Security Act § 1814(a)(2)(B), 42 U.S.C. 1395f(a)(2)(B).

must periodically provide recertification supporting material in accordance with regulations.⁹⁸

Requirements for, and assuring quality of care in, Skilled Nursing Facilities⁹⁹

Requirements related to provision of services

Quality Assessment and Assurance

Every nursing facility must maintain a quality assessment and assurance committee that meets quarterly to identify issues needing quality improvement¹⁰⁰ and to develop and implement appropriate plans of action to correct identified quality deficiencies.¹⁰¹

Clinical Records

Skilled nursing facilities must, with the patient's permission, permit representatives of the state ombudsman to examine such patient's clinical records.¹⁰² The record must contain an assessment of each patient's functional capacity and a plan of care for each patient,¹⁰³ and documentation of the reasons for any discharge or transfer.¹⁰⁴

Residents' Assessments

Assessments must be conducted upon admission¹⁰⁵ and at least once every 12 months.¹⁰⁶ The facility must examine each resident at least once every three months and revise the assessment as necessary;¹⁰⁷ if a significant change in the resident's condition has occurred, a new assessment must be conducted.¹⁰⁸ A registered professional nurse must conduct, coordinate, sign and certify the completeness of assessments; any other health professional completing a portion of the assessment must sign that portion and certify its accuracy.¹⁰⁹ The assessment must describe the resident's ability to perform daily life functions and identify any significant impairment in the resident's functional capacity¹¹⁰ or any medical problems.¹¹¹

Plans of Care

A team including the resident's physician and a registered nurse must prepare the plan of care¹¹² based on the results of the patient assessment.¹¹³ The plan must identify the

⁹⁸ Social Security Act § 1814(a), 42 U.S.C. 1395f(a).

⁹⁹ Social Security Act § 1819, 42 U.S.C. 1395i-3.

¹⁰⁰ Social Security Act § 1819(b)(1)(B)(i), 42 U.S.C. 1395i-3(b)(1)(B)(i).

¹⁰¹ Social Security Act § 1819(b)(1)(B)(ii), 42 U.S.C. 1395i-3(b)(1)(B)(ii).

¹⁰² Social Security Act § 1819(c)(3)(E), 42 U.S.C. 1395i-3(c)(3)(E).

¹⁰³ Social Security Act § 1819(b)(6)(C), 42 U.S.C. 1395i-3(b)(6)(C).

¹⁰⁴ Social Security Act § 1819(c)(2)(B)(i)(II), 42 U.S.C. 1395i-3(c)(2)(B)(i)(II).

¹⁰⁵ Social Security Act § 1819(b)(3)(C)(i)(I), 42 U.S.C. 1395i-3(b)(3)(C)(i)(I).

¹⁰⁶ Social Security Act § 1819(b)(3)(C)(i)(III), 42 U.S.C. 1395i-3(b)(3)(C)(i)(III).

¹⁰⁷ Social Security Act § 1819(b)(3)(C)(ii), 42 U.S.C. 1395i-3(b)(3)(C)(ii).

¹⁰⁸ Social Security Act § 1819(b)(3)(C)(i)(II), 42 U.S.C. 1395i-3(b)(3)(C)(i)(II).

¹⁰⁹ Social Security Act § 1819(b)(3)(B)(i), 42 U.S.C. 1395i-3(b)(3)(B)(i).

¹¹⁰ Social Security Act § 1819(b)(3)(A)(i), 42 U.S.C. 1395i-3(b)(3)(A)(i).

¹¹¹ Social Security Act § 1819(b)(3)(A)(iv), 42 U.S.C. 1395i-3(b)(3)(A)(iv).

¹¹² Social Security Act § 1819(b)(2)(B), 42 U.S.C. 1395i-3(b)(2)(B).

¹¹³ Social Security Act § 1819(b)(3)(D), 42 U.S.C. 1395i-3(b)(3)(D).

medical, nursing and psychosocial needs of the resident and describe how such needs will be met.¹¹⁴ The team must review and revise the plan after every resident assessment.¹¹⁵

Requirements Relating to Residents' Rights

General Rights

The facility must protect and promote the rights of every resident, which include:

- The right to participate in planning care and treatment;¹¹⁶
- The right to privacy with regard to medical treatment;¹¹⁷
- The right to confidentiality of personal and clinical records and to access to current clinical records upon request, within 24 hours of making such request;¹¹⁸
- The right to request and receive access to current clinical records;¹¹⁹
- The right to voice grievances with respect to treatment or care that is (or fails to be) furnished, without discrimination or reprisal, and to prompt efforts by the facility to resolve these grievances and;¹²⁰
- The right to review the results of the most recent survey of the facility conducted by the Secretary or a state and any plan of correction in effect.¹²¹

Provision of Care

In dispensing psychopharmacologic drugs, the facility must maintain plans written by a physician that indicate the need for and proper administration of such drugs; these plans must be annually reviewed for appropriateness by an external consultant.¹²² In using restraints, the facility must maintain written orders of a physician specifying the duration and circumstances under which restraints are to be used.¹²³

Transfers and Discharges

When transferring or discharging patients, the facility must notify the resident and an immediate family member or legal representative of the impending occurrence of and reasons for the transfer or discharge at least 30 days prior to the transfer or discharge, unless otherwise indicated.¹²⁴ The basis for a transfer or discharge must be documented in the resident's clinical record¹²⁵ by an appropriate provider.¹²⁶

Requirements Relating to Administration

¹¹⁴ Social Security Act § 1819(b)(2)(A), 42 U.S.C. 1395i-3(b)(2)(A).

¹¹⁵ Social Security Act § 1819(b)(2)(C), 42 U.S.C. 1395i-3(b)(2)(C).

¹¹⁶ Social Security Act § 1819(c)(1)(A)(i), 42 U.S.C. 1395i-3(c)(1)(A)(i).

¹¹⁷ Social Security Act § 1819(c)(1)(A)(iii), 42 U.S.C. 1395i-3(c)(1)(A)(iii).

¹¹⁸ Social Security Act § 1819(c)(1)(A)(iv), 42 U.S.C. 1395i-3(c)(1)(A)(iv).

¹¹⁹ Social Security Act § 1819(c)(1)(A)(iv), 42 U.S.C. 1395i-3(c)(1)(A)(iv).

¹²⁰ Social Security Act § 1819(c)(1)(A)(vi), 42 U.S.C. 1395i-3(c)(1)(A)(vi).

¹²¹ Social Security Act § 1819(c)(1)(A)(ix), 42 U.S.C. 1395i-3(c)(1)(A)(ix).

¹²² Social Security Act § 1819(c)(1)(D), 42 U.S.C. 1395i-3(c)(1)(D).

¹²³ Social Security Act § 1819(c)(1)(A)(ii), 42 U.S.C. 1395i-3(c)(1)(A)(ii).

¹²⁴ Social Security Act § 1819(c)(2)(B)(ii), 42 U.S.C. 1395i-3(c)(2)(B)(ii).

¹²⁵ Social Security Act § 1819(c)(2)(B)(i)(II), 42 U.S.C. 1395i-3(c)(2)(B)(i)(II).

¹²⁶ Social Security Act § 1819(c)(2)(A), 42 U.S.C. 1395i-3(c)(2)(A).

The facility must have reports with respect to any surveys, certifications, and complaint investigations respecting the facility during the preceding three years available for any individual to review upon request,¹²⁷ and may not make available any identifying information about the complainants or residents.¹²⁸ The facility must post the results of its most recent survey in an accessible location.¹²⁹

A public nurse aide registry must be established¹³⁰ that includes all documented findings of resident neglect, abuse or misappropriation of property by a nurse aide, and any statement of the aide disputing the findings.¹³¹

Definitions of Services, Institutions, Etc.¹³²

A utilization review plan of a skilled nursing facility is sufficient if it provides for review of admissions to the institution, the duration of stays therein, and the professional services furnished with respect to the medical necessity of the services¹³³ and for the purpose of promoting the most efficient use of available health facilities and services.¹³⁴ The plan must provide for prompt notification to the institution, the individual and his attending physician of any finding that further stay in the institution is not medically necessary.¹³⁵

Survey and Certification Process

State and Federal Responsibility

The Secretary is responsible for certifying the compliance of state skilled nursing facilities with the requirements of this section; the state is responsible for certifying compliance of private skilled nursing facilities with these requirements.¹³⁶

Investigation of Allegations of Resident Neglect and Abuse and Misappropriation of Property

Through the agency responsible for surveys and certification of nursing facilities, the state must provide for methods of receiving, reviewing and investigating allegations of patient neglect or abuse and misappropriation of resident property by any individual providing nurse aide services to a nursing facility resident.¹³⁷ If the state finds that a nurse aide neglected or abused a resident or misappropriated resident property in a facility, the state must notify the aide and the registry of such finding; if the state finds that any other individual used by the facility to provide nurse aide services has neglected

¹²⁷ Social Security Act § 1819(d)(1)(D)(i), 42 U.S.C. 1395i-3(d)(1)(D)(i).

¹²⁸ Social Security Act § 1819(d)(1)(D), 42 U.S.C. 1395i-3(d)(1)(D).

¹²⁹ Social Security Act § 1819(c)(8), 42 U.S.C. 1395i-3(c)(8).

¹³⁰ Social Security Act § 1819(e)(2)(A), 42 U.S.C. 1395i-3(e)(2)(A).

¹³¹ Social Security Act § 1819(e)(2)(B), 42 U.S.C. 1395i-3(e)(2)(B).

¹³² Social Security Act § 1861, 42 U.S.C. 1395x.

¹³³ Social Security Act § 1861(k)(1)(A), 42 U.S.C. 1395x(k)(1)(A).

¹³⁴ Social Security Act § 1861(k)(1)(B), 42 U.S.C. 1395x(k)(1)(B).

¹³⁵ Social Security Act § 1861(k)(4), 42 U.S.C. 1395x(k)(4).

¹³⁶ Social Security Act § 1819(g)(1)(A), 42 U.S.C. 1395i-3(g)(1)(A).

¹³⁷ Social Security Act § 1819(g)(1)(C), 42 U.S.C. 1395i-3(g)(1)(C).

or abused a resident or misappropriated resident property in a facility, the state must notify the appropriate licensure authority.¹³⁸

Investigation of Complaints and Monitoring Compliance

The state must maintain procedures to investigate any violation of requirements of this section related to provision of services, residents' rights and administration,¹³⁹ and must monitor facilities that are, were or are suspected to be non-compliant with these requirements.¹⁴⁰

Survey and Certification Process

For purposes of certifying compliance, each skilled nursing facility will be subject to a standard survey conducted without any prior notice¹⁴¹ at least every fifteen months¹⁴² Each survey will include, for a case-mix sample of residents:

- A survey of the quality of care furnished;¹⁴³
- An audit of resident assessments to determine accuracy;¹⁴⁴
- A review of plans of care to determine adequacy;¹⁴⁵ and
- A review of compliance with residents' rights.¹⁴⁶

If a skilled nursing facility is found to have provided substandard quality of care, the facility will be subject to an extended survey,¹⁴⁷ which will identify the policies and procedures that produced the substandard care and determine whether the facility has otherwise complied with nursing facility requirements.¹⁴⁸ Within two months of either a standard survey or an extended survey conducted by the state, the Secretary will conduct validation surveys of a sample of nursing facilities to determine whether the state's survey was adequate.¹⁴⁹ If the Secretary has reason to question the compliance of a particular facility with requirements, the Secretary may conduct a special survey of compliance.¹⁵⁰ The Secretary will also conduct a "special focus facility" program for skilled nursing facilities that have been identified as substantially failing to meet requirements;¹⁵¹ under this program, the Secretary will conduct surveys of facilities at least once every six months.¹⁵²

Disclosure of Results of Inspections and Activities

¹³⁸ Social Security Act § 1819(g)(1)(C), 42 U.S.C. 1395i-3(g)(1)(C).

¹³⁹ Social Security Act § 1819(g)(4)(A), 42 U.S.C. 1395i-3(g)(4)(A).

¹⁴⁰ Social Security Act § 1819(g)(4)(B), 42 U.S.C. 1395i-3(g)(4)(B).

¹⁴¹ Social Security Act § 1819(g)(2)(A)(i), 42 U.S.C. 1395i-3(g)(2)(A)(i).

¹⁴² Social Security Act § 1819(g)(2)(A)(iii)(I), 42 U.S.C. 1395i-3(g)(2)(A)(iii)(I).

¹⁴³ Social Security Act § 1819(g)(2)(A)(i)(I), 42 U.S.C. 1395i-3(g)(2)(A)(i)(I).

¹⁴⁴ Social Security Act § 1819(g)(2)(A)(i)(II), 42 U.S.C. 1395i-3(g)(2)(A)(i)(II).

¹⁴⁵ Social Security Act § 1819(g)(2)(A)(i)(II), 42 U.S.C. 1395i-3(g)(2)(A)(i)(II).

¹⁴⁶ Social Security Act § 1819(g)(2)(A)(i)(III), 42 U.S.C. 1395i-3(g)(2)(A)(i)(III).

¹⁴⁷ Social Security Act § 1819(g)(2)(B)(i), 42 U.S.C. 1395i-3(g)(2)(B)(i).

¹⁴⁸ Social Security Act § 1819(g)(2)(B)(iii), 42 U.S.C. 1395i-3(g)(2)(B)(iii).

¹⁴⁹ Social Security Act § 1819(g)(3)(A), 42 U.S.C. 1395i-3(g)(3)(A).

¹⁵⁰ Social Security Act § 1819(g)(3)(D), 42 U.S.C. 1395i-3(g)(3)(D).

¹⁵¹ Social Security Act § 1819(e)(8)(A), 42 U.S.C. 1395i-3(e)(8)(A).

¹⁵² Social Security Act § 1819(e)(8)(B), 42 U.S.C. 1395i-3(e)(8)(B).

All survey and certification information will be provided to the state's Medicaid fraud and abuse control unit¹⁵³ and be made public.¹⁵⁴ The state must notify the long-term care ombudsman of any non-compliance and of adverse actions taken against a facility.¹⁵⁵ If a skilled nursing facility is found to have provided substandard quality of care, the state must notify each affected resident's attending physician,¹⁵⁶ and the state board responsible for the licensing of the nursing facility administrator.¹⁵⁷ Each state will submit information respecting any survey or certification made respecting a nursing facility, including enforcement actions taken by the state, to the Secretary; the Secretary will use this information to update the information provided on the Nursing Home Compare website.¹⁵⁸

Nursing Home Compare Website

The Department of Health and Human Services will maintain a "Nursing Home Compare" Medicare website.¹⁵⁹ The Secretary will ensure that the information provided on the website includes:

- Resident census data and data on the hours of care provided per resident per day;¹⁶⁰
- Inspection reports, complaint investigation reports and plans of correction;¹⁶¹
- Summary information on the number, type, severity, and outcome of substantiated complaints;¹⁶²
- The number of adjudicated instances of criminal violations committed inside the facility by the employees of a facility;¹⁶³ and
- The number of violations or crimes committed inside the facility that were violations or crimes of abuse, neglect, exploitation, criminal sexual abuse, or other violations or crimes that resulted in serious bodily injury.¹⁶⁴

Home and Community-Based Care

Hospice¹⁶⁵

The Secretary will collect data and information appropriate to revise payments for hospice care,¹⁶⁶ including the number of days of hospice care attributable to Part A

¹⁵³ Social Security Act § 1819(g)(5)(D), 42 U.S.C. 1395i-3(g)(5)(D).

¹⁵⁴ Social Security Act § 1819(g)(5)(A), 42 U.S.C. 1395i-3(g)(5)(A).

¹⁵⁵ Social Security Act § 1819(g)(5)(B), 42 U.S.C. 1395i-3(g)(5)(B).

¹⁵⁶ Social Security Act § 1819(g)(5)(C)(i), 42 U.S.C. 1395i-3(g)(5)(C)(i).

¹⁵⁷ Social Security Act § 1819(g)(5)(C)(ii), 42 U.S.C. 1395i-3(g)(5)(C)(ii).

¹⁵⁸ Social Security Act § 1819(g)(5)(E), 42 U.S.C. 1395i-3(g)(5)(E).

¹⁵⁹ Social Security Act § 1819(i)(1)(A), 42 U.S.C. 1395i-3(i)(1)(A).

¹⁶⁰ Social Security Act § 1819(i)(1)(A)(i), 42 U.S.C. 1395i-3(i)(1)(A)(i).

¹⁶¹ Social Security Act § 1819(i)(1)(A)(ii), 42 U.S.C. 1395i-3(i)(1)(A)(ii).

¹⁶² Social Security Act § 1819(i)(1)(A)(iv), 42 U.S.C. 1395i-3(i)(1)(A)(iv).

¹⁶³ Social Security Act § 1819(i)(1)(A)(v)(I), 42 U.S.C. 1395i-3(i)(1)(A)(v)(I).

¹⁶⁴ Social Security Act § 1819(i)(1)(A)(v)(II), 42 U.S.C. 1395(i)(1)(A)(v)(II).

¹⁶⁵ Social Security Act § 1814, 42 U.S.C. 1395f; Social Security Act § 1861, 42 U.S.C. 1395x.

¹⁶⁶ Social Security Act § 1814(i)(6)(A), 42 U.S.C. 1395f(i)(6)(A).

enrollees,¹⁶⁷ the number¹⁶⁸ and length of hospice visits and other basic information with respect to the visit.¹⁶⁹

Home Health¹⁷⁰

Every home health provider¹⁷¹ must certify, as appropriate,¹⁷² a beneficiary's need for home health services, and must periodically provide materials for recertification in accordance with regulations.¹⁷³

Home health agencies must include the individual's plan of care in the patient's clinical records.¹⁷⁴

Every home health agency must protect and promote the rights of each individual under its care including:¹⁷⁵

- The right to be fully informed in advance about the care and treatment to be provided and to participate in planning care and treatment;¹⁷⁶
- The right to voice grievances with respect to treatment or care that is or fails to be furnished, without discrimination or reprisal for voicing grievances;¹⁷⁷ and
- The right to confidentiality of clinical records.¹⁷⁸

Every three years,¹⁷⁹ each home health agency will be subject to a standard survey.¹⁸⁰

Within two months of receiving a significant number of complaints about the agency, a standard survey will be conducted.¹⁸¹ A standard survey will include:

- Visits to the homes of a sample of individuals to evaluate whether the furnished items and services attained and maintained the highest practicable functional capacity of the individual as reflected in the written plan of care and clinical records,¹⁸² and
- A survey of the quality of furnished care and services as measured by indicators of medical, nursing and rehabilitative care.¹⁸³

¹⁶⁷ Social Security Act § 1814(i)(6)(B)(ii), 42 U.S.C. 1395f(i)(6)(B)(ii).

¹⁶⁸ Social Security Act § 1814(i)(6)(B)(v), 42 U.S.C. 1395f(i)(6)(B)(v).

¹⁶⁹ Social Security Act § 1814(i)(6)(B)(vii), 42 U.S.C. 1395f(i)(6)(B)(vii).

¹⁷⁰ Social Security Act § 1814, 42 U.S.C. 1395f; Social Security Act § 1861, 42 U.S.C. 1395x; Social Security Act § 1891, 42 U.S.C. 1395bbb; Social Security Act § 1895, 42 U.S.C. 1395fff.

¹⁷¹ Provider = a physician, or for (B) services, a physician, an NP, a clinical nurse specialist or a PA who does not have a direct/indirect employment relationship with the facility but is working in collaboration with a physician

¹⁷² Social Security Act § 1814(a), 42 U.S.C. 1395f(a).

¹⁷³ Social Security Act § 1814(a), 42 U.S.C. 1395f(a).

¹⁷⁴ Social Security Act § 1861(o)(3), 42 U.S.C. 1395bbb(a)(1).

¹⁷⁵ Social Security Act § 1891(a)(1), 42 U.S.C. 1395bbb(a)(1).

¹⁷⁶ Social Security Act § 1891(a)(1)(A), 42 U.S.C. 1395bbb(a)(1)(A).

¹⁷⁷ Social Security Act § 1891(a)(1)(B), 42 U.S.C. 1395bbb(a)(1)(B).

¹⁷⁸ Social Security Act § 1891(a)(1)(C), 42 U.S.C. 1395bbb(a)(1)(C).

¹⁷⁹ Social Security Act § 1891(c)(2)(A), 42 U.S.C. 1395bbb(c)(2)(A).

¹⁸⁰ Social Security Act § 1891(c)(1), 42 U.S.C. 1395bbb(c)(1).

¹⁸¹ Social Security Act § 1891(c)(2)(B)(ii), 42 U.S.C. 1395bbb(c)(2)(B)(ii).

¹⁸² Social Security Act § 1891(c)(2)(C)(i)(I), 42 U.S.C. 1395bbb(c)(2)(C)(i)(I).

¹⁸³ Social Security Act § 1891(c)(2)(C)(i)(II), 42 U.S.C. 1395bbb(c)(2)(C)(i)(II).

If the standard survey indicates that the agency has provided a substandard quality of care, the agency will be immediately subject to an extended survey to review and identify the policies and procedures which produced such substandard care and to determine whether the agency has complied with the conditions of participation.¹⁸⁴

Program of All-Inclusive Care for the Elderly (PACE)¹⁸⁵

The Secretary or state administering agency will utilize information on an individual's health status and other related indicators, such as medical diagnoses, to determine whether the individual is PACE eligible.¹⁸⁶ This determination will be reevaluated annually.¹⁸⁷

PACE providers will collect data,¹⁸⁸ maintain and afford access to program records, including pertinent medical records, to the Secretary and the state administering agency,¹⁸⁹ and make reports necessary for monitoring the operation and effectiveness of the PACE program available to the Secretary and the state administering agency.¹⁹⁰

If a PACE enrollee ends his enrollment, the program must help the individual obtain necessary transitional care by providing appropriate referrals and making the individual's medical records available to new providers.¹⁹¹ Each PACE provider must have a written plan of quality assurance.¹⁹²

Other Providers and Services¹⁹³

The Secretary will establish and implement quality standards for suppliers of items and services¹⁹⁴ to be applied by independent accreditation organizations.¹⁹⁵ Suppliers must submit evidence of accreditation as meeting applicable quality standards.¹⁹⁶

Rural health clinics must maintain a quality assessment and improvement program.¹⁹⁷ Comprehensive outpatient rehabilitation facilities must have in effect a utilization review plan.¹⁹⁸

¹⁸⁴ Social Security Act § 1891(c)(2)(D), 42 U.S.C. 1395bbb(c)(2)(D).

¹⁸⁵ Social Security Act § 1894, 42 U.S.C. 1395eee.

¹⁸⁶ Social Security Act § 1894(c)(2), 42 U.S.C. 1395eee(c)(2).

¹⁸⁷ Social Security Act § 1894(c)(3)(A), 42 U.S.C. 1395eee(c)(3)(A).

¹⁸⁸ Social Security Act § 1894(e)(3)(A)(i)(I), 42 U.S.C. 1395eee(e)(3)(A)(i)(I).

¹⁸⁹ Social Security Act § 1894(e)(3)(A)(i)(II), 42 U.S.C. 1395eee(e)(3)(A)(i)(II).

¹⁹⁰ Social Security Act § 1894(e)(3)(A)(i)(III), 42 U.S.C. 1395eee(e)(3)(A)(i)(III).

¹⁹¹ Social Security Act § 1894(a)(2)(C), 42 U.S.C. 1395eee(a)(2)(C).

¹⁹² Social Security Act § 1894(b)(2)(A), 42 U.S.C. 1395eee(b)(2)(A).

¹⁹³ Social Security Act § 1834, 42 U.S.C. 1395m; Social Security Act § 1861, 42 U.S.C. 1395x; Social Security Act § 1886, 42 U.S.C. 1395ww.

¹⁹⁴ Defined in Social Security Act § 1834(a)(20)(D), 42 U.S.C. 1395m(a)(20)(D).

¹⁹⁵ Social Security Act § 1834(a)(20)(A), 42 U.S.C. 1395m(a)(20)(A).

¹⁹⁶ Social Security Act § 1834(a)(20)(F)(i), 42 U.S.C. 1395m(a)(20)(F)(i).

¹⁹⁷ Social Security Act § 1861(aa)(2)(I), 42 U.S.C. 1395x(aa)(2)(I).

¹⁹⁸ Social Security Act § 1861(cc)(2)(G), 42 U.S.C. 1395x(cc)(2)(G).

Religious nonmedical health care institutions must have in effect a utilization review plan that includes:

- Review by an appropriate committee of the institution¹⁹⁹ of the following:²⁰⁰
 - Admissions,
 - The duration of stays,
 - Cases of extended duration, and
 - Furnished items and services.
- Provision for the maintenance of records of the meetings, decisions and actions of such committee.²⁰¹

Personalized prevention plan services create a plan for an individual that, among other appropriate elements,²⁰² includes:

- A health risk assessment completed prior to or as part of an individual’s visit with a health professional;²⁰³
- Identification of chronic diseases, injury risks, modifiable risk factors, and urgent health needs of the individual;²⁰⁴
- Establishment or update of the individual’s medical and family history;²⁰⁵
- A lists of current providers and suppliers that are regularly involved in providing care to the individual, including a list of all prescribed medication;²⁰⁶
- Height, weight, BMI, and blood pressure;²⁰⁷
- Detection of any cognitive impairment,²⁰⁸ and
- Establishment or update of a list of risk factors and conditions.²⁰⁹

In order to improve the health status of beneficiaries, the Secretary will encourage the use of, integration with, and coordination of health information technology to aid in the development of self-management skills as well as the management of and adherence to provider recommendations.²¹⁰

Medicare Coverage for End-Stage Renal Disease Patients²¹¹

¹⁹⁹ Social Security Act § 1861(ss)(1)(H)(ii), 42 U.S.C. 1395x(ss)(1)(H)(ii).

²⁰⁰ Social Security Act § 1861(ss)(1)(H)(i), 42 U.S.C. 1395x(ss)(1)(H)(i).

²⁰¹ Social Security Act § 1861(ss)(1)(H)(iii), 42 U.S.C. 1395x(ss)(1)(H)(iii).

²⁰² Social Security Act § 1861(hhh)(2)(G), 42 U.S.C. 1395x(hhh)(2)(G).

²⁰³ Social Security Act § 1861(hhh)(1)(A), 42 U.S.C. 1395x(hhh)(1)(A) (“Health professional” defined in Social Security Act § 1861(hhh)(3), 42 U.S.C. 1395x(hhh)(3)).

²⁰⁴ Social Security Act § 1861(hhh)(4)(A)(i), 42 U.S.C. 1395x(hhh)(4)(A)(i).

²⁰⁵ Social Security Act § 1861(hhh)(2)(A), 42 U.S.C. 1395x(hhh)(2)(A).

²⁰⁶ Social Security Act § 1861(hhh)(2)(B), 42 U.S.C. 1395x(hhh)(2)(B).

²⁰⁷ Social Security Act § 1861(hhh)(2)(C), 42 U.S.C. 1395x(hhh)(2)(C).

²⁰⁸ Social Security Act § 1861(hhh)(2)(D), 42 U.S.C. 1395x(hhh)(2)(D).

²⁰⁹ Social Security Act § 1861(hhh)(2)(E)(ii), 42 U.S.C. 1395x(hhh)(2)(E)(ii).

²¹⁰ Social Security Act § 1861(hhh)(4)(F), 42 U.S.C. 1395x(hhh)(4)(F).

²¹¹ Social Security Act § 1881, 42 U.S.C. 1395rr.

The network administrative organization of each renal disease network area will be responsible for developing criteria and standards relating to the quality and appropriateness of patient care;²¹² implementing a procedure for evaluating and resolving patient grievances;²¹³ submitting an annual report to the Secretary which shall include data on the network's performance in meeting its goals, including the comparative performance of facilities and providers with respect to the identification and placement of suitable candidates in self-care settings and transplantation and encouraging participation in vocational rehabilitation programs;²¹⁴ and collecting, validating, and analyzing such data as are necessary to prepare these reports²¹⁵ for all facilities and providers of renal disease services located within its network area.²¹⁶ The Secretary will establish a national end stage renal disease registry to assemble and analyze the data reported by network organizations²¹⁷ that will permit an identification of the economic impact, cost-effectiveness and medical efficacy of alternative modalities of treatment;²¹⁸ and the determination of patient mortality and morbidity rates, trends in such rates, and other indices of quality of care.²¹⁹

Each provider or facility must meet or exceed a total performance score with respect to performance measures established by the Secretary,²²⁰ which include measures of patient satisfaction.²²¹ The Secretary will make public the information regarding performance²²² after giving the facility the opportunity to review the information.²²³ The Secretary will provide certificates that indicate the total performance score to providers of services and renal dialysis facilities;²²⁴ each facility receiving a certificate shall prominently display the certificate at the facility.²²⁵ The Secretary will establish a list of providers of services that indicates the total performance score and the performance score for individual measures that will be posted on CMS' website.²²⁶

Administration

Medicare Payment Advisory Commission²²⁷

With respect to the Medicare + Choice program under Part D, the Commission shall review the development and implementation of mechanisms to assure the quality of care

²¹² Social Security Act § 1881(c)(2)(B), 42 U.S.C. 1395rr(c)(2)(B).

²¹³ Social Security Act § 1881(c)(2)(D), 42 U.S.C. 1395rr(c)(2)(D).

²¹⁴ Social Security Act § 1881(c)(2)(H), 42 U.S.C. 1395rr(c)(2)(H).

²¹⁵ Social Security Act § 1881(c)(2)(F), 42 U.S.C. 1395rr(c)(2)(F).

²¹⁶ Social Security Act § 1881(c)(1)(A)(i)(II), 42 U.S.C. 1395rr(c)(1)(A)(i)(II).

²¹⁷ Social Security Act § 1881(c)(7), 42 U.S.C. 1395rr(c)(7).

²¹⁸ Social Security Act § 1881(c)(7)(B), 42 U.S.C. 1395rr(c)(7)(B).

²¹⁹ Social Security Act § 1881(c)(7)(D), 42 U.S.C. 1395rr(c)(7)(D).

²²⁰ Social Security Act § 1881(h)(1)(B), 42 U.S.C. 1395rr(h)(1)(B).

²²¹ Social Security Act § 1881(h)(2)(A)(ii), 42 U.S.C. 1395rr(h)(2)(A)(ii).

²²² Social Security Act § 1881(h)(6)(A), 42 U.S.C. 1395rr(h)(6)(A).

²²³ Social Security Act § 1881(h)(6)(B), 42 U.S.C. 1395rr(h)(6)(B).

²²⁴ Social Security Act § 1881(h)(6)(C)(i), 42 U.S.C. 1395rr(h)(6)(C)(i).

²²⁵ Social Security Act § 1881(h)(6)(C)(ii), 42 U.S.C. 1395rr(h)(6)(C)(ii).

²²⁶ Social Security Act § 1881(h)(6)(D), 42 U.S.C. 1395rr(h)(6)(D).

²²⁷ Social Security Act § 1805, 42 U.S.C. 1395b-6.

for enrollees,²²⁸ as well as the impact of the Medicare+Choice program on enrollees' access to care.²²⁹ With respect to the payment policies under Parts A and B, the Commission shall review the relationship of payment policies to access and quality of care for Medicare beneficiaries.²³⁰

Provisions Relating to Administration²³¹

The Medicare Beneficiary Ombudsman will receive complaints, grievances and requests for information about any aspect of the Medicare program submitted by Part A and/or B enrollees.²³² The Ombudsman will provide assistance with such complaints, grievances and requests, including collecting relevant information for such individuals.²³³

Determinations; appeals²³⁴

Qualified independent contractors will review initial determinations as to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury with respect to benefits under Part A or B and will base any decisions with respect to the reconsideration on applicable information, including the medical records of the individual involved and other medical, technical and scientific evidence.²³⁵ In making expedited reconsiderations, the qualified independent contract will solicit the views of the individual involved²³⁶ and will notify by telephone and in writing the individual and the provider of services and attending physician of the individual the results of the reconsideration.²³⁷

Each qualified independent contractor will maintain accurate records of each decision made in an electronic database²³⁸ in a manner that provides for identification of the specific claim that gave rise to appeals,²³⁹ situations suggesting the need for increased education for providers of services, physicians or suppliers,²⁴⁰ and situations suggesting the need for changes in national or local coverage determinations.²⁴¹ The contractor will permit access to and use of any such information and records as the Secretary may require.²⁴² Each contractor will annually submit to the Secretary these records for the previous year.²⁴³

²²⁸ Social Security Act § 1805(b)(2)(A)(iv), 42 U.S.C. 1395b-6(b)(2)(A)(iv).

²²⁹ Social Security Act § 1805(b)(2)(A)(v), 42 U.S.C. 1395b-6(b)(2)(A)(v).

²³⁰ Social Security Act § 1805(b)(2)(B)(iii), 42 U.S.C. 1395b-6(b)(2)(B)(iii).

²³¹ Social Security Act § 1808, 42 U.S.C. 1395b-9.

²³² Social Security Act § 1808(c)(2)(A), 42 U.S.C. 1395b-9(c)(2)(A).

²³³ Social Security Act § 1808(c)(2)(B)(i), 42 U.S.C. 1395b-9(c)(2)(B)(i).

²³⁴ Social Security Act § 1869, 42 U.S.C. 1395ff.

²³⁵ Social Security Act § 1869(c)(3)(B)(i), 42 U.S.C. 1395ff(c)(3)(B)(i).

²³⁶ Social Security Act § 1869(c)(3)(C)(iii)(II), 42 U.S.C. 1395ff(c)(3)(C)(iii)(II).

²³⁷ Social Security Act § 1869(c)(3)(C)(iii)(I), 42 U.S.C. 1395ff(c)(3)(C)(iii)(I).

²³⁸ Social Security Act § 1869(c)(3)(I)(ii), 42 U.S.C. 1395ff(c)(3)(I)(ii).

²³⁹ Social Security Act § 1869(c)(3)(I)(ii)(I), 42 U.S.C. 1395ff(c)(3)(I)(ii)(I).

²⁴⁰ Social Security Act § 1869(c)(3)(I)(ii)(II), 42 U.S.C. 1395ff(c)(3)(I)(ii)(II).

²⁴¹ Social Security Act § 1869(c)(3)(I)(ii)(III), 42 U.S.C. 1395ff(c)(3)(I)(ii)(III).

²⁴² Social Security Act § 1869(c)(3)(I)(i), 42 U.S.C. 1395ff(c)(3)(I)(i).

²⁴³ Social Security Act § 1869(c)(3)(I)(iii), 42 U.S.C. 1395ff(c)(3)(I)(i).

At least once every five years, the Secretary will conduct a survey of a sample of individuals who have filed appeals of determinations to determine the satisfaction of such individuals with the process for appeals.²⁴⁴ The Secretary will submit a report to Congress describing the results of this survey.²⁴⁵

Certification of Medicare Supplemental Health Insurance Policies²⁴⁶

There are specific restrictions on supplemental health insurance policies from requesting or requiring genetic testing of an individual or his or her family members.²⁴⁷ However, an issuer of a supplemental health policy may obtain and use the results of a genetic test to make payment determinations.²⁴⁸ A supplemental health insurer may, under specific circumstances, request that an individual or family member undergo a genetic test for research purposes,²⁴⁹ but may not require it.²⁵⁰ In general, an issuer of supplemental health insurance may not request, require or purchase genetic information for underwriting purposes or for enrollment purposes.²⁵¹

Medicare Integrity Program²⁵²

The Medicare Integrity Program will promote the integrity of the Medicare program by entering into contracts with eligible entities to carry out its activities,²⁵³ such as review of activities of individuals and entities furnishing items and services for which payment may be made under this title, including medical and utilization review and fraud review.²⁵⁴

Independent Medicare Advisory Board²⁵⁵

The independent Medicare advisory board will annually produce a public report containing standardized information on system-wide health care costs, patient access to care, utilization, and quality-of-care.²⁵⁶ Each report will include information on the quality and costs of care for the population at the most local level practicable,²⁵⁷ beneficiary and consumer access to care, patient experience of care,²⁵⁸ epidemiological

²⁴⁴ Social Security Act § 1869(e)(4)(B), 42 U.S.C. 1395ff(e)(4)(B).

²⁴⁵ Social Security Act § 1869(e)(4)(B), 42 U.S.C. 1395ff(e)(4)(B).

²⁴⁶ Social Security Act § 1882, 42 U.S.C. 1395ss.

²⁴⁷ Social Security Act § 1882(x)(1)(A), 42 U.S.C. 1395ss(x)(1)(A).

²⁴⁸ Social Security Act § 1882(x)(1)(C), 42 U.S.C. 1395ss(x)(1)(C).

²⁴⁹ The research must comply with 45 C.F.R. Part 46 and any other applicable state or federal laws concerning human subject research.

²⁵⁰ Social Security Act § 1882(x)(1)(D), 42 U.S.C. 1395ss(x)(1)(D).

²⁵¹ Social Security Act § 1882(x)(2), 42 U.S.C. 1395ss(x)(2).

²⁵² Social Security Act § 1893, 42 U.S.C. 1395ddd.

²⁵³ Social Security Act § 1893(a), 42 U.S.C. 1395ddd(a).

²⁵⁴ Social Security Act § 1893(b)(1), 42 U.S.C. 1395ddd(b)(1).

²⁵⁵ Social Security Act § 1899A, 42 U.S.C. 1395kkk.

²⁵⁶ Social Security Act § 1899A(n)(1), 42 U.S.C. 1395kkk(n)(1).

²⁵⁷ Social Security Act § 1899A(n)(2)(A), 42 U.S.C. 1395kkk(n)(2)(A).

²⁵⁸ Social Security Act § 1899A(n)(2)(B), 42 U.S.C. 1395kkk(n)(2)(B).

shifts and demographic changes,²⁵⁹ and the proliferation, effectiveness and utilization of health care technologies.²⁶⁰

Protecting residents of long-term care facilities²⁶¹

The National Training Institute for surveyors will analyze and report annually on the total number and sources of complaints of abuse, neglect and misappropriation of property,²⁶² the extent to which such complaints are referred to law enforcement agencies,²⁶³ and the general results of federal and state investigations of such complaints.²⁶⁴

*Payments to HMOs and Competitive Medical Plans*²⁶⁵

The HMO must provide meaningful procedures for hearing and resolving grievances between the organization and its enrolled members.²⁶⁶ The organization must have arrangements for an ongoing quality assurance program for health care services it provides to its enrolled members, which stresses health outcomes²⁶⁷ and provides review by health care professionals of the process followed in the provision of such health care services.²⁶⁸ Each contract will provide that the Secretary has the right to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract²⁶⁹ and shall have the right to audit and inspect any books and records of the eligible organization that pertain to services performed under the contract.²⁷⁰

Each risk-sharing contract with an HMO will provide that the organization will maintain a written agreement with a utilization and quality control peer review organization.²⁷¹ Each contract will provide that the organization may not operate a physician incentive plan that places a physician at substantial financial risk for services not provided by the physician unless the organization conducts periodic surveys of individuals currently and formerly enrolled to determine the degree of access of such individuals to services provided by the organization and satisfaction with the quality of such services.²⁷²

Quality Measurement

²⁵⁹ Social Security Act § 1899A(n)(2)(C), 42 U.S.C. 1395kkk(n)(2)(C).

²⁶⁰ Social Security Act § 1899A(n)(2)(D), 42 U.S.C. 1395kkk(n)(2)(D).

²⁶¹ 42 U.S.C. 1395i-3a.

²⁶² 42 U.S.C. 1395i-3a(1)(B)(vii)(I).

²⁶³ 42 U.S.C. 1395i-3a(1)(B)(vii)(II).

²⁶⁴ 42 U.S.C. 1395i-3a(1)(B)(vii)(III).

²⁶⁵ Social Security Act § 1876, 42 U.S.C. 1395mm.

²⁶⁶ Social Security Act § 1876(c)(5)(A), 42 U.S.C. 1395mm(c)(5)(A).

²⁶⁷ Social Security Act § 1876(c)(6)(A), 42 U.S.C. 1395mm(c)(6)(A).

²⁶⁸ Social Security Act § 1876(c)(6)(B), 42 U.S.C. 1395mm(c)(6)(B).

²⁶⁹ Social Security Act § 1876(i)(3)(A)(i)(I), 42 U.S.C. 1395mm(i)(3)(A)(i)(I).

²⁷⁰ Social Security Act § 1876(i)(3)(A)(ii)(II), 42 U.S.C. 1395mm(i)(3)(A)(ii)(II).

²⁷¹ Social Security Act § 1876(i)(7)(A), 42 U.S.C. 1395mm(i)(7)(A).

²⁷² Social Security Act § 1876(i)(8)(A)(ii)(II), 42 U.S.C. 1395mm(i)(8)(A)(ii)(II).

Contract with a consensus-based entity regarding performance measurement²⁷³

The Secretary will have in effect a contract with a consensus-based entity, such as the National Quality Forum,²⁷⁴ that makes recommendations on an integrated national strategy and priorities for health care performance measurement.²⁷⁵ The entity will provide for the endorsement of standardized health care performance measures,²⁷⁶ and will promote the use and development of electronic health records that contain the functionality for automated collection, aggregation, and transmission of performance measurement information.²⁷⁷ The entity will annually submit a report to Congress and the Secretary describing its recommendations,²⁷⁸ the implementation of quality and efficiency measurement initiatives, the coordination of such initiatives implemented by other payers,²⁷⁹ and gaps in quality and efficiency measures, including those reflected in the priority areas of the National Quality Strategy.²⁸⁰

Quality and Efficiency Measurement²⁸¹

In selecting quality and efficiency measures to be used in the various provisions of the Social Security Act, and for public reporting of performance information, the Secretary must obtain input from a multi-stakeholder group.²⁸² The Secretary must also include an assessment of the quality and efficiency impact of the use of endorsed measures²⁸³ that is made available to the public.²⁸⁴

The following providers must annually submit data on quality measures to the Secretary. Each provider will have an opportunity to review such data, which will then be made publicly available and reported on CMS' website.

- Hospice programs,²⁸⁵
- Home health agencies,²⁸⁶
- Rehabilitation facilities,²⁸⁷
- Hospitals²⁸⁸ providing outpatient services,²⁸⁹

²⁷³ Social Security Act § 1890, 42 U.S.C. 1395aaa.

²⁷⁴ Social Security Act § 1890(a)(1), 42 U.S.C. 1395aaa(a)(1).

²⁷⁵ Social Security Act § 1890(b)(1), 42 U.S.C. 1395aaa(b)(1).

²⁷⁶ Social Security Act § 1890(b)(2), 42 U.S.C. 1395aaa(b)(2).

²⁷⁷ Social Security Act § 1890(b)(4), 42 U.S.C. 1395aaa(b)(4).

²⁷⁸ Social Security Act § 1890(b)(5)(A)(ii), 42 U.S.C. 1395aaa(b)(5)(A)(ii).

²⁷⁹ Social Security Act § 1890(b)(5)(A)(i), 42 U.S.C. 1395aaa(b)(5)(A)(i).

²⁸⁰ Social Security Act § 1890(b)(5)(A)(iv), 42 U.S.C. 1395aaa(b)(5)(A)(iv).

²⁸¹ Social Security Act § 1890A, 42 U.S.C. 1395aaa-1.

²⁸² Social Security Act § 1890A(a)(1), 42 U.S.C. 1395aaa-1(a)(1); For provisions using the quality and efficiency measure, see Social Security Act § 1890(b)(7)(B), 42 U.S.C. 1395aaa(b)(7)(B).

²⁸³ Social Security Act § 1890A(a)(6)(A), 42 U.S.C. 1395aaa-1(a)(6)(A).

²⁸⁴ Social Security Act § 1890A(a)(6)(B), 42 U.S.C. 1395aaa-1(a)(6)(B).

²⁸⁵ Social Security Act § 1814(i)(5), 42 U.S.C. 1395f(i)(5) (requirement applies beginning in 2014).

²⁸⁶ Social Security Act § 1895(b)(3)(B)(v), 42 U.S.C. 1395fff(b)(3)(B)(v).

²⁸⁷ Social Security Act § 1886(i)(7), 42 U.S.C. 1395ww(i)(7) (requirement applies beginning in 2014).

²⁸⁸ Does not include psychiatric hospitals, rehabilitation hospitals, hospitals whose patients are predominantly under 18, long-term care hospitals (average length of stay over 25 days). Social Security Act § 1886(d)(1)(B), 42 U.S.C. 1395ww(d)(1)(B).

- Cancer hospitals,²⁹⁰
- Long-term care hospitals^{291, 292},
- Psychiatric hospitals and units.²⁹³
- Inpatient rehabilitation hospitals²⁹⁴

Every service provider must agree to release its patient data to a peer review organization in order for such organization to review the utilization and quality of health care services furnished by the provider.²⁹⁵ In addition to providing access to data, the following providers must maintain an agreement with a utilization and quality control peer review organization that has a contract with the Secretary under Title XI, Part B:

- Home health agencies,²⁹⁶
- Hospitals, including critical access hospitals,²⁹⁷ and
 - With respect to inpatient services provided by a hospital, the organization will specifically review the validity of diagnostic information provided by the hospital, the completeness, adequacy and quality of care provided, and the appropriateness of admissions, discharges and the care provided.²⁹⁸
- HMOs.²⁹⁹

Demonstration/Research

Chronic Care Improvement³⁰⁰

The Secretary shall establish programs for the improvement of chronic care, which shall be designed to improve clinical quality and beneficiary satisfaction for targeted enrollees with one or more “threshold conditions.”³⁰¹ The developmental phase of these programs (Phase 1), will involve the development, testing and evaluation of chronic care improvement programs in select geographic areas by chronic care improvement organizations.³⁰² The Secretary will contract for independent evaluations by a contractor with knowledge of chronic care management programs to assess specific program factors, including quality improvement measures, beneficiary and provider satisfaction and health outcomes.³⁰³ The implementation phase (Phase 2) involves program expansion to additional geographic areas, which is conditioned upon the program improving the

²⁸⁹ Social Security Act §1833(t)(17), 42 U.S.C. 1395l(t)(17).

²⁹⁰ Social Security Act § 1866(k), 42 U.S.C. 1395cc(k) (requirement applies beginning in 2014).

²⁹¹ Social Security Act § 1886(m)(5), 42 U.S.C. 1395ww(m)(5).

²⁹² Social Security Act § 1886(b)(3)(B)(viii)(VII), 42 U.S.C. 1395ww(b)(3)(B)(viii)(VII).

²⁹³ Social Security Act § 1886(s)(4), 42 U.S.C. 1395ww(s)(4) (requirement applies beginning in 2014).

²⁹⁴ Social Security Act § 1886(j)(7), 42 U.S.C. 1395ww(j)(7) (requirement applies beginning in 2014).

²⁹⁵ Social Security Act § 1866(a)(1)(E)(i), 42 U.S.C. 1395cc(a)(1)(E)(i).

²⁹⁶ Social Security Act § 1866(a)(1)(F)(ii), 42 U.S.C. 1395cc(a)(1)(F)(ii).

²⁹⁷ Social Security Act § 1866(a)(1)(F)(ii), 42 U.S.C. 1395cc(a)(1)(F)(ii).

²⁹⁸ Social Security Act § 1866(a)(1)(F)(i), 42 U.S.C. 1395cc(a)(1)(F)(i) (the organization will review).

²⁹⁹ Social Security Act § 1876(i)(7)(A), 42 U.S.C. 1395mm(i)(7)(A).

³⁰⁰ Social Security Act § 1807, 42 U.S.C. 1395b-8.

³⁰¹ Social Security Act § 1807(a)(1), 42 U.S.C. 1395b-8(a)(1).

³⁰² Social Security Act § 1807(b)(1), 42 U.S.C. 1395b-8(b)(1).

³⁰³ Social Security Act § 1807(b)(5), 42 U.S.C. 1395b-8(b)(5).

clinical quality of care and beneficiary satisfaction.³⁰⁴ Each program will have a process to screen targeted beneficiaries for conditions other than threshold conditions in order to develop an individualized, goal-oriented care management plan,³⁰⁵ which will be provided to each participating beneficiary.³⁰⁶ This care management plan will include self-care education for the beneficiary³⁰⁷ and the use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information.³⁰⁸ In carrying out the care management plan, the organization operating the care improvement program will guide the participant in managing his health and in performing activities specified under the elements of his care management plan³⁰⁹ and will develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.³¹⁰ The organization will monitor and report to the Secretary on health care quality, cost and outcomes.³¹¹

Addressing Health Care Disparities³¹²

The Secretary evaluated approaches for collection of Medicare data that allow for the evaluation of disparities in health care services and performance on the basis of race, ethnicity, and gender.³¹³ In conducting such evaluation, the Secretary considered the objective of protecting patient privacy.³¹⁴ The Secretary submitted to Congress a report on this evaluation that identified approaches for identifying, collecting and evaluating data on health care disparities for the original fee-for-service program under Parts A and B, the Medicare Advantage program under Part C and the Medicare prescription drug program under Part D.³¹⁵ In the report, the Secretary included recommendations on the most effective strategies and approaches to reporting HEDIS quality measures (as required under § 1852(e)(3)) and other nationally recognized quality performance measures on the basis of race, ethnicity and gender.³¹⁶ By 24 months, the Secretary will implement the approaches identified in this report for the ongoing, accurate and timely collection and evaluation of data on health care disparities.³¹⁷ By four years, and every four years thereafter, the Secretary will submit a report to Congress that includes recommendations for improving the identification of health care disparities for Medicare beneficiaries based on analyses of the data collected using these approaches.³¹⁸

Demonstration of application of physician volume increases to group practices³¹⁹

³⁰⁴ Social Security Act § 1807(c)(2), 42 U.S.C. 1395b-8(c)(2).

³⁰⁵ Social Security Act § 1807(e)(1)(A), 42 U.S.C. 1395b-8(e)(1)(A).

³⁰⁶ Social Security Act § 1807(e)(1)(B), 42 U.S.C. 1395b-8(e)(1)(B).

³⁰⁷ Social Security Act § 1807(e)(2)(B), 42 U.S.C. 1395b-8(e)(2)(B).

³⁰⁸ Social Security Act § 1807(e)(2)(D), 42 U.S.C. 1395b-8(e)(2)(D).

³⁰⁹ Social Security Act § 1807(e)(3)(A), 42 U.S.C. 1395b-8(e)(3)(A).

³¹⁰ Social Security Act § 1807(e)(3)(C), 42 U.S.C. 1395b-8(e)(3)(C).

³¹¹ Social Security Act § 1807(e)(4)(A), 42 U.S.C. 1395b-8(e)(4)(A).

³¹² Social Security Act § 1809, 42 U.S.C. 1395b-10.

³¹³ Social Security Act § 1809(a), 42 U.S.C. 1395b-10(a).

³¹⁴ Social Security Act § 1809(a)(1), 42 U.S.C. 1395b-10(a)(1).

³¹⁵ Social Security Act § 1809(b)(1)(A), 42 U.S.C. 1395b-10(b)(1)(A).

³¹⁶ Social Security Act § 1809(b)(1)(B), 42 U.S.C. 1395b-10(b)(1)(B).

³¹⁷ Social Security Act § 1809(c), 42 U.S.C. 1395b-10(c).

³¹⁸ Social Security Act § 1809(b)(2), 42 U.S.C. 1395b-10(b)(2).

³¹⁹ Social Security Act § 1866A, 42 U.S.C. 1395cc-1.

The Secretary will conduct demonstration projects to test, and if proven effective, expand the use of incentives to participating health care groups that encourage coordination of care furnished to Part A and B enrollees and other providers, practitioners, and suppliers of health care items and services,³²⁰ encourage investment in administrative structures and processes to ensure efficient service delivery³²¹ and reward physicians for improving health outcomes.³²²

Provisions for administration of demonstration program³²³

The Secretary will establish performance standards for the demonstration program including standards for quality of health care items and services, cost-effectiveness and beneficiary satisfaction.³²⁴ The Secretary is authorized to disclose to an entity with a program administration contract such information, including medical information, on individuals receiving health care items and services under the program as the entity may require to carry out its responsibilities under the contract.³²⁵ The Secretary may require entities with agreements to provide health care items or services under the demonstration program, and entities with program administration contracts to maintain adequate records, afford the Secretary access to such records and to furnish such reports and materials as the Secretary may require for purposes of implementation, oversight, and evaluation of the program and of individuals' and entities' effectiveness in performance of such agreements or contracts.³²⁶ In order to participate in the demonstration program, an entity must guarantee that it will not deny, limit or condition the coverage or provision of benefits for eligible individuals based on any health status-related factor described in § 2702 of the Public Health Service Act.³²⁷ Two years from the date of enactment, and biennially thereafter for six years, the Secretary will report to Congress on the use of authorities under the demonstration program, addressing the impact of the use of those authorities on expenditures, access and quality under the programs.³²⁸

Health Care Quality Demonstration Program³²⁹

The Secretary will establish a demonstration program under which she will approve demonstration projects that examine health delivery factors that encourage the delivery of improved quality in patient care,³³⁰ including: the provision of incentives to improve the safety of care provided to beneficiaries;³³¹ reduced scientific uncertainty in the delivery

³²⁰ Social Security Act § 1866A(a)(1)(A), 42 U.S.C. 1395cc-1(a)(1)(A).

³²¹ Social Security Act § 1866A(a)(1)(B), 42 U.S.C. 1395cc-1(a)(1)(B).

³²² Social Security Act § 1866A(a)(1)(C), 42 U.S.C. 1395cc-1(a)(1)(C).

³²³ Social Security Act § 1866B, 42 U.S.C. 1395cc-2.

³²⁴ Social Security Act § 1866B(a)(5), 42 U.S.C. 1395cc-2(a)(5).

³²⁵ Social Security Act § 1866B(b)(9), 42 U.S.C. 1395cc-2(b)(9).

³²⁶ Social Security Act § 1866B(c)(1), 42 U.S.C. 1395cc-2(c)(1).

³²⁷ Social Security Act § 1866B(c)(3), 42 U.S.C. 1395cc-2(c)(3).

³²⁸ Social Security Act § 1866B(f), 42 U.S.C. 1395cc-2(f).

³²⁹ Social Security Act § 1866C, 42 U.S.C. 1395cc-3.

³³⁰ Social Security Act § 1866C(b), 42 U.S.C. 1395cc-3(b).

³³¹ Social Security Act § 1866C(b)(1), 42 U.S.C. 1395cc-3(b)(1).

of care through the examination of variations in the utilization and allocation of services, and outcomes measurement and research;³³² encourage shared decision making between providers and patients;³³³ the provision of incentives for improving the quality and safety of care and achieving the efficient allocation of resources;³³⁴ and the appropriate use of culturally and ethnically sensitive health care delivery.³³⁵

To be eligible to participate in this program, an entity must meet quality standards established by the Secretary,³³⁶ including: the implementation of continuous quality improvement mechanisms that are aimed at integrating community-based support services, primary care, and referral care;³³⁷ the implementation of activities to increase the delivery of effective care to beneficiaries;³³⁸ encouraging patient participation in preference-based decisions;³³⁹ and the implementation of activities to encourage the coordination and integration of medical service delivery.³⁴⁰

In carrying out this program, the Secretary may direct the Director of the National Institutes of Health to expand the efforts of the Institutes to evaluate current medical technologies and improve the foundation for evidence-based practice;³⁴¹ the Administrator of the Agency for Healthcare Research and Quality to, where possible and appropriate, use the program under this section as a laboratory for the study of quality improvement strategies and to evaluate, monitor, and disseminate information relevant to such program;³⁴² and the Administrator of the Centers for Medicare and Medicaid Services and the Administrator of the Center for Medicare Choices to support linkages of relevant Medicare data to registry information from participating health care groups for the beneficiary populations served by the participating groups, for analysis supporting the purposes of the demonstration program, consistent with the applicable provisions of the Health Insurance Portability and Accountability Act of 1996.³⁴³

National Pilot Program on Payment Bundling³⁴⁴

The Secretary will establish a pilot program for integrated care during an episode of care³⁴⁵ provided to an applicable beneficiary³⁴⁶ around a hospitalization in order to

³³² Social Security Act § 1866C(b)(3), 42 U.S.C. 1395cc-3(b)(3).

³³³ Social Security Act § 1866C(b)(4), 42 U.S.C. 1395cc-3(b)(4).

³³⁴ Social Security Act § 1866C(b)(5), 42 U.S.C. 1395cc-3(b)(5).

³³⁵ Social Security Act § 1866C(b)(6), 42 U.S.C. 1395cc-3(b)(6).

³³⁶ Social Security Act § 1866C(d)(2), 42 U.S.C. 1395cc-3(d)(2).

³³⁷ Social Security Act § 1866C(d)(2)(A), 42 U.S.C. 1395cc-3(d)(2)(A).

³³⁸ Social Security Act § 1866C(d)(2)(B), 42 U.S.C. 1395cc-3(d)(2)(B).

³³⁹ Social Security Act § 1866C(d)(2)(C), 42 U.S.C. 1395cc-3(d)(2)(C).

³⁴⁰ Social Security Act § 1866C(d)(2)(D), 42 U.S.C. 1395cc-3(d)(2)(D).

³⁴¹ Social Security Act § 1866C(h)(1), 42 U.S.C. 1395cc-3(h)(1).

³⁴² Social Security Act § 1866C(h)(2), 42 U.S.C. 1395cc-3(h)(2).

³⁴³ Social Security Act § 1866C(h)(3), 42 U.S.C. 1395cc-3(h)(3).

³⁴⁴ Social Security Act § 1866D, 42 U.S.C. 1395cc-4.

³⁴⁵ Episode of care is defined in Social Security Act § 1866D(a)(2)(D), 42 U.S.C. 1395cc-4(a)(2)(D).

³⁴⁶ “Applicable beneficiary” is defined as an individual who is admitted to a hospital for an applicable condition and is entitled to, or enrolled for, benefits under part A and enrolled for benefits under part B, but not enrolled under part C or a PACE program. Social Security Act § 1866D(a)(2)(A), 42 U.S.C. 1395cc-

improve the coordination, quality and efficiency of health care services. A payment methodology tested under the pilot program will include payment for the furnishing of applicable services,³⁴⁷ such as care coordination, medication reconciliation, discharge planning, transitional care services and other patient-centered activities.³⁴⁸ The Secretary will establish quality measures related to care provided by participating entities.³⁴⁹ Quality measures will include measures of functional status improvement,³⁵⁰ reducing rates of avoidable hospital readmissions,³⁵¹ rates of admission to an emergency room after a hospitalization,³⁵² incidence of health care acquired infections,³⁵³ measures of patient-centeredness of care,³⁵⁴ and measures of patient perception of care.³⁵⁵ An entity will submit data to the Secretary on these quality measures during each year of the pilot program.³⁵⁶ To the extent practicable, the Secretary will specify that data on measures be submitted through use of a qualified electronic health record.³⁵⁷ The Secretary will conduct an independent evaluation of the pilot program,³⁵⁸ including the extent to which the program has improved quality measures,³⁵⁹ health outcomes,³⁶⁰ and applicable beneficiary access to care.³⁶¹ The Secretary will submit to Congress a report on the initial results of this independent evaluation two years after the pilot program has been implemented³⁶² and within three years after implementation, will send Congress the final results of this evaluation.³⁶³

Independence at home Medical Practice Demonstration Program³⁶⁴

The Secretary will conduct a demonstration program to test a payment incentive and service delivery model that utilizes a physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes for applicable beneficiaries³⁶⁵ in the provision of items and services.³⁶⁶ The program will test whether such a model, which is accountable for providing comprehensive, coordinated, continuous and accessible care to high-need populations at home and

4(a)(2)(A). “Applicable condition” means 1 or more of 10 conditions selected by the Secretary. Social Security Act § 1866D(a)(2)(B), 42 U.S.C. 1395cc-4(a)(2)(A).

³⁴⁷ “Applicable services” is defined in Social Security Act § 1866D(a)(2)(C), 42 U.S.C. 1395cc-4(a)(2)(C).

³⁴⁸ Social Security Act § 1866D(c)(3)(B), 42 U.S.C. 1395cc-4(c)(3)(B).

³⁴⁹ Social Security Act § 1866D(c)(4)(A), 42 U.S.C. 1395cc-4(c)(4)(A).

³⁵⁰ Social Security Act § 1866D(c)(4)(A)(i), 42 U.S.C. 1395cc-4(c)(4)(A)(i).

³⁵¹ Social Security Act § 1866D(c)(4)(A)(ii), 42 U.S.C. 1395cc-4(c)(4)(A)(ii).

³⁵² Social Security Act § 1866D(c)(4)(A)(iv), 42 U.S.C. 1395cc-4(c)(4)(A)(iv).

³⁵³ Social Security Act § 1866D(c)(4)(A)(v), 42 U.S.C. 1395cc-4(c)(4)(A)(v).

³⁵⁴ Social Security Act § 1866D(c)(4)(A)(vii), 42 U.S.C. 1395cc-4(c)(4)(A)(vii).

³⁵⁵ Social Security Act § 1866D(c)(4)(A)(viii), 42 U.S.C. 1395cc-4(c)(4)(A)(viii).

³⁵⁶ Social Security Act § 1866D(c)(4)(B)(i), 42 U.S.C. 1395cc-4(c)(4)(B)(i).

³⁵⁷ Social Security Act § 1866D(c)(4)(B)(ii), 42 U.S.C. 1395cc-4(c)(4)(B)(ii).

³⁵⁸ Social Security Act § 1866D(e)(1), 42 U.S.C. 1395cc-4(e)(1).

³⁵⁹ Social Security Act § 1866D(e)(1)(A), 42 U.S.C. 1395cc-4(e)(1)(A).

³⁶⁰ Social Security Act § 1866D(e)(1)(B), 42 U.S.C. 1395cc-4(e)(1)(B).

³⁶¹ Social Security Act § 1866D(e)(1)(C), 42 U.S.C. 1395cc-4(e)(1)(C).

³⁶² Social Security Act § 1866D(e)(2)(A), 42 U.S.C. 1395cc-4(e)(2)(A).

³⁶³ Social Security Act § 1866D(e)(2)(B), 42 U.S.C. 1395cc-4(e)(2)(B).

³⁶⁴ Social Security Act § 1866E, 42 U.S.C. 1395cc-5.

³⁶⁵ “Applicable beneficiary” is defined in Social Security Act § 1866E(d)(1), 42 U.S.C. 1395cc-5(d)(1).

³⁶⁶ Social Security Act § 1866E(a)(1), 42 U.S.C. 1395cc-5(a)(1).

coordinating health care across all treatment settings,³⁶⁷ results in: reducing preventable hospitalizations;³⁶⁸ preventing hospital readmissions;³⁶⁹ reducing emergency room visits;³⁷⁰ improving health outcomes commensurate with the beneficiaries' stage of chronic illness;³⁷¹ improving the efficiency of care, such as by reducing duplicative diagnostic and laboratory tests;³⁷² and achieving beneficiary and family caregiver satisfaction.³⁷³

An independence at home medical practice³⁷⁴ must use electronic health information systems, remote monitoring and mobile diagnostic technology.³⁷⁵ The entity will report on quality measures and such data as the Secretary determines is appropriate to monitor and evaluate the demonstration program.³⁷⁶ The Secretary will evaluate each independence at home medical practice under the program to assess whether the practice achieved the results discussed above,³⁷⁷ and will monitor data on quality of services after an applicable beneficiary discontinues receiving services through a qualifying practice.³⁷⁸ The Secretary will conduct an independent evaluation of the demonstration program and submit to Congress a final report including best practices under the program, which will include an analysis of the program on coordination of care, applicable beneficiary access to services, and the quality of health care services provided.³⁷⁹

Shared Savings Program³⁸⁰

The Secretary will establish a shared savings program that promotes accountability for a patient population and coordinates items and services under Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.³⁸¹ Under such program, groups of providers of services and suppliers may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an Accountable Care Organization.³⁸² Accountable Care Organizations that meet quality performance standards are eligible to receive payments for shared savings.³⁸³ The Accountable Care Organization must be willing to become accountable for the quality and overall care of the Medicare fee-for-service beneficiaries

³⁶⁷ Social Security Act § 1866E(a)(2), 42 U.S.C. 1395cc-5(a)(2).

³⁶⁸ Social Security Act § 1866E(a)(2)(A), 42 U.S.C. 1395cc-5(a)(2)(A).

³⁶⁹ Social Security Act § 1866E(a)(2)(B), 42 U.S.C. 1395cc-5(a)(2)(B).

³⁷⁰ Social Security Act § 1866E(a)(2)(C), 42 U.S.C. 1395cc-5(a)(2)(C).

³⁷¹ Social Security Act § 1866E(a)(2)(D), 42 U.S.C. 1395cc-5(a)(2)(D).

³⁷² Social Security Act § 1866E(a)(2)(E), 42 U.S.C. 1395cc-5(a)(2)(E).

³⁷³ Social Security Act § 1866E(a)(2)(G), 42 U.S.C. 1395cc-5(a)(2)(G).

³⁷⁴ "Independence at home medical practice" is defined in Social Security Act § 1866E(b)(1)(A), 42 U.S.C. 1395cc-5(b)(1)(A).

³⁷⁵ Social Security Act § 1866E(b)(1)(A)(vi), 42 U.S.C. 1395cc-5(b)(1)(A)(vi).

³⁷⁶ Social Security Act § 1866E(b), 42 U.S.C. 1395cc-5(b).

³⁷⁷ Social Security Act § 1866E(f)(1), 42 U.S.C. 1395cc-5(f)(1).

³⁷⁸ Social Security Act § 1866E(f)(2), 42 U.S.C. 1395cc-5(f)(2).

³⁷⁹ Social Security Act § 1866E(g), 42 U.S.C. 1395cc-5(g).

³⁸⁰ Social Security Act § 1899, 42 U.S.C. 1395jjj.

³⁸¹ Social Security Act § 1899(a)(1), 42 U.S.C. 1395jjj(a)(1).

³⁸² Social Security Act § 1899(a)(1)(A), 42 U.S.C. 1395jjj(a)(1)(A).

³⁸³ Social Security Act § 1899(a)(1)(B), 42 U.S.C. 1395jjj(a)(1)(B).

assigned to it³⁸⁴ and must define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, coordinate care such as through the use of telehealth, remote patient monitoring and other such enabling technologies³⁸⁵ and demonstrate to the Secretary that it meets patient-centeredness criteria, such as the use of patient assessments or individualized care plans.³⁸⁶ The Secretary will determine appropriate measures to assess the quality of care furnished by the Accountable Care Organizations,³⁸⁷ such as measures of clinical process and outcomes,³⁸⁸ patient experience of care,³⁸⁹ and utilization, such as rates of hospital admissions for ambulatory care sensitive conditions.³⁹⁰ An Accountable Care Organization will submit data to the Secretary in order to evaluate the quality of care furnished by the Accountable Care Organization; such data may include transitions across health care setting, including hospital discharge planning.³⁹¹ The Secretary will establish quality performance standards to assess the quality of care furnished by Accountable Care Organizations.³⁹² The Secretary may incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (S.S.A. §1848), including such requirements related to electronic health records and electronic prescribing.³⁹³

PART C – Medicare + Choice Program

Medicare Part C, also called Medicare Advantage, is a private health plan that provides Medicare enrollees with coverage for Parts A (hospital insurance) and B (medical insurance). Most of the plans also include prescription drug coverage, which is known as Part D. The federal government contributes funds to the Medicare Advantage plans, which also collect premiums from enrollees.³⁹⁴

Eligibility, Election and Enrollment³⁹⁵

In an effort to promote an active, informed selection among coverage options, the Secretary will provide information to current and potential Medicare beneficiaries³⁹⁶ about Medicare + Choice plans including plan quality and performance indicators for benefits under the plan, including information on Medicare enrollee satisfaction and information on health outcomes.³⁹⁷

³⁸⁴ Social Security Act § 1899(b)(2)(A), 42 U.S.C. 1395jjj(b)(2)(A).

³⁸⁵ Social Security Act § 1899(b)(2)(G), 42 U.S.C. 1395jjj(b)(2)(G).

³⁸⁶ Social Security Act § 1899(b)(2)(H), 42 U.S.C. 1395jjj(b)(2)(H).

³⁸⁷ Social Security Act § 1899(b)(3)(A), 42 U.S.C. 1395jjj(b)(3)(A).

³⁸⁸ Social Security Act § 1899(b)(3)(A)(i), 42 U.S.C. 1395jjj(b)(3)(A)(i).

³⁸⁹ Social Security Act § 1899(b)(3)(A)(ii), 42 U.S.C. 1395jjj(b)(3)(A)(ii).

³⁹⁰ Social Security Act § 1899(b)(3)(A)(iii), 42 U.S.C. 1395jjj(b)(3)(A)(iii).

³⁹¹ Social Security Act § 1899(b)(3)(B), 42 U.S.C. 1395jjj(b)(3)(B).

³⁹² Social Security Act § 1899(b)(3)(C), 42 U.S.C. 1395jjj(b)(3)(C).

³⁹³ Social Security Act § 1899(b)(3)(D), 42 U.S.C. 1395jjj(b)(3)(D).

³⁹⁴ “Medicare Advantage,” Available at: <http://www.medicare.gov/navigation/medicare-basics/medicare-benefits/part-c.aspx>.

³⁹⁵ Social Security Act § 1851, 42 U.S.C. 1395w-21.

³⁹⁶ Social Security Act § 1851(d)(1), 42 U.S.C. 1395w-21(d)(1).

³⁹⁷ Social Security Act § 1851(d)(4)(D), 42 U.S.C. 1395w-21(d)(4)(D).

Benefits and Beneficiary Protections³⁹⁸

A Medicare + Choice organization may not deny, limit or condition coverage or provision of benefits for individuals based on any health status-related factor described in § 2702(a)(1) of the Public Health Service Act.³⁹⁹

Each Medicare Advantage organization shall have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees in each Medicare Advantage plan.⁴⁰⁰ As part of this quality improvement program, each Medicare Advantage organization will have a chronic care improvement program; such program will have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions.⁴⁰¹ Also as part of this program, each Medicare Advantage organization will provide for the collection, analysis and reporting of data that permits the measurement of health outcomes and other indices of quality.⁴⁰²

The Secretary shall biennially submit to Congress a report regarding how quality assurance programs focus on racial and ethnic minorities.⁴⁰³ Each report will include an evaluation of the impact of such programs on eliminating health disparities and on improving health outcomes, continuity and coordination of care, management of chronic conditions and consumer satisfaction,⁴⁰⁴ as well as recommendations on ways to reduce clinical outcome disparities among racial and ethnic minorities.⁴⁰⁵

Each Medicare + Choice organization must provide meaningful procedures for hearing and resolving grievances between the organization and enrollees with Medicare+Choice plans.⁴⁰⁶

To the extent that a Medicare+Choice organization maintains medical records or other health information regarding enrollees, the organization will establish procedures to safeguard the privacy of any individually identifiable enrollee information⁴⁰⁷ and to assure timely access of enrollees to such records and information.⁴⁰⁸

Payments to Medicare+Choice Organizations⁴⁰⁹

³⁹⁸ Social Security Act § 1852, 42 U.S.C. 1395w-22.

³⁹⁹ Social Security Act § 1852(b)(1)(A), 42 U.S.C. 1395w-22(b)(1)(A).

⁴⁰⁰ Social Security Act § 1852(e)(1), 42 U.S.C. 1395w-22(e)(1).

⁴⁰¹ Social Security Act § 1852(e)(2), 42 U.S.C. 1395w-22(e)(2).

⁴⁰² Social Security Act § 1852(e)(3), 42 U.S.C. 1395w-22(e)(3).

⁴⁰³ Social Security Act § 1852(e)(5)(A), 42 U.S.C. 1395w-22(e)(5)(A).

⁴⁰⁴ Social Security Act § 1852(e)(5)(B)(ii), 42 U.S.C. 1395w-22(e)(5)(B)(ii).

⁴⁰⁵ Social Security Act § 1852(e)(5)(B)(iii), 42 U.S.C. 1395w-22(e)(5)(B)(iii).

⁴⁰⁶ Social Security Act § 1852(f), 42 U.S.C. 1395w-22(f).

⁴⁰⁷ Social Security Act § 1852(h)(1), 42 U.S.C. 1395w-22(h)(1).

⁴⁰⁸ Social Security Act § 1852(h)(3), 42 U.S.C. 1395w-22(h)(3).

⁴⁰⁹ Social Security Act § 1853, 42 U.S.C. 1395w-23.

The Secretary will adjust payment amounts to Medicare+Choice organizations for such risk factors as health status to ensure actuarial equivalence.⁴¹⁰ For purposes of this adjustment and with respect to special needs individuals with chronic health conditions, the Secretary will use a risk score that reflects the known underlying risk profile and chronic health status of similar individuals.⁴¹¹ The Secretary will annually evaluate and revise this system in order to account for higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions and individuals with a diagnosis of mental illness.⁴¹² The Secretary will require Medicare+Choice organizations to submit data regarding inpatient hospital services⁴¹³ in order to develop a report on the method of risk adjustment of payment rates that accounts for variations in costs based on health status.⁴¹⁴

Contracts with Medicare+Choice Organizations⁴¹⁵

Each contract with a Medicaid + Choice Organization shall provide that the Secretary shall have the right to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract.⁴¹⁶ In conjunction with this periodic audit, the Secretary will conduct a review to ensure that the organization is meeting the requirements of 1859(f)(5).⁴¹⁷

Definitions, Miscellaneous Provisions⁴¹⁸

Organizations offering specialized Medicare Advantage plans for special needs individuals must conduct an initial assessment and an annual assessment of the individual's physical, psychosocial, and functional needs;⁴¹⁹ develop a plan in consultation with the individual (if feasible) that identifies goals and objectives, including measurable outcomes as well as specific services and benefits to be provided;⁴²⁰ and use an interdisciplinary team in the management of care.⁴²¹

PART D – Voluntary Prescription Drug Benefit Program

Part D provides prescription drug coverage to Medicare enrollees. There is a late enrollment penalty if an enrollee does not join when he or she is first eligible. The

⁴¹⁰ Social Security Act §1853(a)(1)(C)(i), 42 U.S.C. 1395w-23(a)(1)(C)(i).

⁴¹¹ Social Security Act § 1853(a)(1)(C)(iii)(I), 42 U.S.C. 1395w-23(a)(1)(C)(iii)(I).

⁴¹² Social Security Act § 1853(a)(1)(C)(iii)(III), 42 U.S.C. 1395w-23(a)(1)(C)(iii)(III).

⁴¹³ Social Security Act § 1853(a)(3)(B), 42 U.S.C. 1395w-23(a)(3)(B).

⁴¹⁴ Social Security Act § 1853(a)(3)(A), 42 U.S.C. 1395w-23(a)(3)(A).

⁴¹⁵ Social Security Act § 1857, 42 U.S.C. 1395w-27.

⁴¹⁶ Social Security Act § 1857(d)(2)(A), 42 U.S.C. 1395w-27(d)(2)(A).

⁴¹⁷ Social Security Act § 1857(d)(6), 42 U.S.C. 1395w-27(d)(6).

⁴¹⁸ Social Security Act § 1859, 42 U.S.C. 1395w-28.

⁴¹⁹ Social Security Act § 1859(f)(5)(B)(i), 42 U.S.C. 1395w-28(f)(5)(B)(i).

⁴²⁰ Social Security Act § 1859(f)(5)(B)(ii), 42 U.S.C. 1395w-28(f)(5)(B)(ii).

⁴²¹ Social Security Act § 1859(f)(5)(B)(iii), 42 U.S.C. 1395w-28(f)(5)(B)(iii).

prescription drug coverage is provided by a Medicare approved insurance company or private company. Part D includes cost sharing by enrollees.⁴²²

Subpart 1 – Part D Eligible Individuals and Prescription Drug Benefits

Eligibility, Enrollment and Information⁴²³

The Secretary may provide to each Prescription Drug Plan sponsor and each Medicare Advantage organization such identifying information about Part D eligible individuals as the Secretary determines to be necessary to facilitate efficient marketing of and enrollment in prescription drug plans and Medicare Advantage-Part D plans.⁴²⁴

Beneficiary Protections for Qualified Prescription Drug Coverage⁴²⁵

The PDP sponsor will have in place, with respect to covered Part D drugs, a cost-effective drug utilization management program,⁴²⁶ quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use,⁴²⁷ a medication therapy management program⁴²⁸ and a program to control fraud, waste and abuse.⁴²⁹ A medication therapy management program is a program that may be furnished by a pharmacist that is designed to assure, with respect to targeted beneficiaries,⁴³⁰ that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions.⁴³¹ Such a program may include elements that promote detection of adverse drug events and patterns of overuse and underuse of prescription drugs.⁴³² Beginning in 2012, PDP sponsors shall offer medication therapy management services to targeted beneficiaries that must include an annual comprehensive medication review furnished face-to-face or using telehealth technologies by a qualified provider,⁴³³ and follow-up interventions as warranted based on the findings of the annual review.⁴³⁴

⁴²² “Medicare Prescription Drug Coverage,” Available at: <http://www.medicare.gov/navigation/medicare-basics/medicare-benefits/part-d.aspx>.

⁴²³ Social Security Act § 1860D-1, 42 U.S.C. 1395w-101.

⁴²⁴ Social Security Act § 1860D-1(b)(4)(A), 42 U.S.C. 1395w-101(b)(4)(A).

⁴²⁵ Social Security Act § 1860D-4, 42 U.S.C. 1395w-104.

⁴²⁶ Social Security Act § 1860D-4(c)(1)(A), 42 U.S.C. 1395w-104(c)(1)(A).

⁴²⁷ Social Security Act § 1860D-4(c)(1)(B), 42 U.S.C. 1395w-104(c)(1)(B).

⁴²⁸ Social Security Act § 1860D-4(c)(1)(C), 42 U.S.C. 1395w-104(c)(1)(C).

⁴²⁹ Social Security Act § 1860D-4(c)(1)(D), 42 U.S.C. 1395w-104(c)(1)(D).

⁴³⁰ A targeted beneficiary is one who has multiple chronic diseases, is taking multiple covered part D drugs and is identified as likely to incur annual costs that exceed a level specified by the Secretary (Social Security Act § 1860D-4(c)(2)(A)(ii), 42 U.S.C. 1395w-104(c)(2)(A)(ii)).

⁴³¹ Social Security Act § 1860D-4(c)(2)(A)(i), 42 U.S.C. 1395w-104(c)(2)(A)(i).

⁴³² Social Security Act § 1860D-4(c)(2)(B)(iii), 42 U.S.C. 1395w-104(c)(2)(B)(iii).

⁴³³ Social Security Act § 1860D-4(c)(2)(C)(i), 42 U.S.C. 1395w-104(c)(2)(C)(i).

⁴³⁴ Social Security Act § 1860D-4(c)(2)(C)(ii), 42 U.S.C. 1395w-104(c)(2)(C)(ii).

The PDP sponsor shall have in place a process to assess, at least on a quarterly basis, the medication use of individuals who are at risk but not enrolled in the medication therapy management program.⁴³⁵

The Secretary will establish guidelines for the coordination of any medication therapy management program with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program.⁴³⁶

Prescriptions and other information for covered Part D drugs prescribed for Part D eligible individuals that are transmitted electronically shall be transmitted in accordance with the electronic prescription program.⁴³⁷ The electronic prescription program will provide for the electronic transmittal of information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed upon request of the professional or pharmacist involved.⁴³⁸ The Secretary will provide for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs,⁴³⁹ consistent with the objectives of improving patient safety,⁴⁴⁰ the quality of care provided to patients⁴⁴¹ and efficiencies in the delivery of care.⁴⁴²

Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor and enrollees with prescription drug plans.⁴⁴³

To the extent that a PDP Sponsor and prescription drug plan maintains medical records or other health information regarding enrollees, the organization will establish procedures to safeguard the privacy of any individually identifiable enrollee information⁴⁴⁴ and to assure timely access of enrollees to such records and information.⁴⁴⁵

Subpart 2 – Prescription Drug Plans; PDP Sponsors; Financing

PDP Regions; Submission of Bids; Plan Approval⁴⁴⁶

A contract entered into for fallback prescription drug plans will provide for payment of management fees tied to performance measures⁴⁴⁷ established by the Secretary, which

⁴³⁵ Social Security Act § 1860D-4(c)(2)(D), 42 U.S.C. 1395w-104(c)(2)(D).

⁴³⁶ Social Security Act § 1860D-4(c)(2)(F), 42 U.S.C. 1395w-104(c)(2)(F).

⁴³⁷ Social Security Act § 1860D-4(e)(1), 42 U.S.C. 1395w-104(e)(1).

⁴³⁸ Social Security Act § 1860D-4(e)(2)(B), 42 U.S.C. 1395w-104(e)(2)(B).

⁴³⁹ Social Security Act § 1860D-4(e)(3)(A), 42 U.S.C. 1395w-104(e)(3)(A).

⁴⁴⁰ Social Security Act § 1860D-4(e)(3)(B)(i), 42 U.S.C. 1395w-104(e)(3)(B)(i).

⁴⁴¹ Social Security Act § 1860D-4(e)(3)(B)(ii), 42 U.S.C. 1395w-104(e)(3)(B)(ii).

⁴⁴² Social Security Act § 1860D-4(e)(3)(B)(iii), 42 U.S.C. 1395w-104(e)(3)(B)(iii).

⁴⁴³ Social Security Act § 1860D-4(f), 42 U.S.C. 1395w-104(f).

⁴⁴⁴ Social Security Act § 1860D-4(i), 42 U.S.C. 1395w-104(i).

⁴⁴⁵ Social Security Act § 1852(h)(3), 42 U.S.C. 1395w-22(h)(3).

⁴⁴⁶ Social Security Act § 1860D-11, 42 U.S.C. 1395w-111.

⁴⁴⁷ Social Security Act § 1860D-11(g)(5)(A)(ii), 42 U.S.C. 1395w-111(g)(5)(A)(ii).

shall include measures for quality programs, such that the entity provides enrollees with quality programs that avoid adverse drug reactions and overutilization and reduce medical errors.⁴⁴⁸

⁴⁴⁸ Social Security Act §1860D-11(g)(5)(B)(ii), 42 U.S.C. 1395w-11(g)(5)(B)(ii).