1) Provider Agreements and Supplier Approval

a) General

In order to participate in the Medicare program, a provider must meet applicable civil rights laws, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act, and the Age Discrimination Act.[1]

If CMS determines that the provider meets the requirements, it will send the provider written notice of that determination and two copies of the provider agreement. If CMS accepts the agreement, it will return one copy to the provider.[2]

CMS may refuse to enter into an agreement for any of the following reasons:[3]

- Principals of the prospective provider have been convicted of fraud;
- The prospective provider has failed to disclose ownership and control interests;
- The prospective provider is a physician-owned hospital and does not have procedures in place for making physician ownership disclosures to patients; or
- The prospective provider is unable to give satisfactory assurance of compliance with the requirements of Title XVIII of the Act.

b) Essentials of provider agreements

Provider agreements must comply with regulatory requirements.[4] A provider may not charge a Medicare beneficiary for services that the beneficiary is entitled to be paid by Medicare.[5]

A provider may not:[6]

- Require an individual entitled to hospital insurance benefits to prepay for inpatient services as a condition of admittance as an inpatient, except where it is clear upon admission that payment under Medicare cannot be made.

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[1] 42 C.F.R. § 489.10
[2] 42 C.F.R. § 489.11
[3] 42 C.F.R. § 489.12
[4] 42 C.F.R. § 489.20
[5] 42 C.F.R. § 489.21
[6] 42 C.F.R. § 489.22

- Deny covered inpatient services to an individual entitled to have payment made for those services on the ground of inability or failure to pay a requested amount at or before admission.
- Evict, or threaten to evict, an individual for inability to pay a deductible or a coinsurance amount required under Medicare.
- Charge an individual for its agreement to admit or readmit the individual on some specified future date for covered inpatient services; or for failure to remain an inpatient for any agreed-upon length of time or for failure to give advance notice of departure from the provider's facilities.

A provider that furnishes inpatient hospital services to a retired Federal worker age 65 or older who is enrolled in a fee-for-service Federal Employee Health Benefit ("FEHB") plan and who is not covered under Medicare Part A, must accept, as payment in full, an amount that approximates as closely as possible the Medicare inpatient hospital prospective payment system (PPS) rate.[7]

A hospital with an emergency department must treat all patients who seek treatment in the emergency department whether or not the patient is eligible for Medicare benefits and regardless of his or her ability to pay.[8] The hospital will be sanctioned for inappropriate transfers of patients.

For inpatient services, a hospital that participates in the Medicare program must participate in any health plan contracted with Civilian Health and Medical Program of the Uniformed Services and Civilian Health and Medical Program of the Veterans Administration and accept the CHAMPUS/CHAMPVA-determined allowable amount as payment in full.[9]

For inpatient services, a hospital that participates in the Medicare program must admit any veteran whose admission is authorized by the Department of Veterans Affairs.[10]

Any home care agency entering the Medicare program must have available sufficient funds at the time of application submission and at all times during the enrollment process up to the expiration of the 3 month period following the conveyance of Medicare billing privileges to operate the Home Health Agency ("HHA").[11]

Hospitals and critical access hospitals that participate in the Medicare program and furnish inpatient hospital services must accept the payment methodology for health programs provided by the Indian Health Service.[12]

c) Allowable charges

[7] 42 C.F.R. § 489.23
[8] 42 C.F.R. § 489.24
[9] 42 C.F.R. § 489.26
[10] 42 C.F.R. § 489.27
[11] 42 C.F.R. § 489.28
[12] 42 C.F.R. § 489.29

Providers must comply with requirements in how they charge deductibles and coinsurance for Medicare beneficiaries.[13]

- A provider may charge a beneficiary only for the first 3 pints of blood or units of packed red cells furnished under Medicare.[14]
- A provider is permitted to do balance billing if services furnished at the request of the beneficiary are more expensive than services covered under Medicare.[15]
- A hospital receiving payment for a covered hospital stay under either a state reimbursement control system or a demonstration project may charge a beneficiary for noncovered services, specifically custodial care and medically unnecessary care.[16]

d) Handling of incorrect collections

"Incorrect collections" means any amounts collected from a beneficiary that is not authorized. A payment properly made to a provider by an individual not entitled to Medicare benefits will be deemed to be an incorrect collection.[17] A prompt refund to the beneficiary or other person is the preferred method of handling incorrect collections.[18] In order to carry out the commitment to refund amounts incorrectly collected, CMS may determine that amounts offset are to be paid directly to the beneficiary or other person from whom the provider receive the incorrect collection.[19]

e) Termination of a provider agreement

A provider, CMS, and the Office of the Inspector General may terminate a provider agreement.[20] The public must be provided notice before the effective date of termination. Payment is available for up to 30 days after the effective date of termination for inpatient hospital services, home health services, and hospice care.[21] When a provider agreement has been terminated by CMS or the OIG, a new agreement with that provider will not be accepted unless CMS or the OIG finds that the reason for termination of the previous agreement has been removed and there is reasonable assurance that it will not recur and that the provider has fulfilled all of the statutory and regulatory responsibilities of its previous agreement.[22]

f) Advance directives

Hospitals, critical access hospitals, skilled nursing facilities, home health agencies, providers of home health care, hospices and religious nonmedical health care institutions must maintain written policies and procedures concerning advance directives.[23]

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[13] 42 C.F.R. § 489.30
[14] 42 C.F.R. § 489.31
[15] 42 C.F.R. § 489.32
[16] 42 C.F.R. § 489.34
[17] 42 C.F.R. § 489.40
[18] 42 C.F.R. § 489.41
[19] 42 C.F.R. § 489.42
[20] 42 C.F.R. §§ 489.52 through 489.54
[21] 42 C.F.R. § 489.55
[22] 42 C.F.R. § 489.57
[23] 42 C.F.R. § 489.102

2) Survey, Certification, and Enforcement Procedures

a) General

i. National accreditation organizations

A national accreditation organization seeking approval for deeming authority for Medicare requirements must furnish detailed information and materials to CMS.[24]

A national accreditation program must provide reasonable assurance to CMS that it requires the providers or suppliers it accredits to meet requirements that are at least as stringent as the Medicare conditions when taken as a whole.[25] In such a case, CMS may deem the providers or suppliers the program accredits to be in compliance with the appropriate Medicare conditions. These providers and suppliers are subject to validation surveys.

CMS must review national accreditation organizations to ensure that they comply with regulatory requirements.[26] CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and to assess the organization's compliances with its own policies and procedures as part of the application review process, the validation review process, or the continuing oversight of an accreditation organization's performance.[27]

ii. Providers, suppliers, and hospitals

In order to be approved for participation in or for coverage under the Medicare program, a prospective provider or supplier must meet statutory definitions under the Social Security Act and comply with long-term care regulatory requirements.[28]

Hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or American Osteopathic Association (AOA) are deemed to meet all of the Medicare conditions of participation for hospitals except: the requirement for utilization review; additional special staffing and medical records requirements related to psychiatric hospitals; and any other requirement that is considered as being higher or more precise than the requirements for accreditation.[29]

CMS may require a survey of an accredited provider or supplier to validate its organization's accreditation process.[30] If a validation survey results in a finding that a provider or supplier is out of compliance with one or more Medicare conditions, the provider or supplier will no longer be deemed to meet any Medicare conditions.

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[24] 42 C.F.R. § 488.4
[25] 42 C.F.R. § 488.6
[26] 42 C.F.R. § 488.8
[27] 42 C.F.R. § 488.9
[28] 42 C.F.R. § 488.3
[29] 42 C.F.R. § 488.5
[30] 42 C.F.R. § 488.7

iii. State survey agencies

State and local agencies may perform the following functions: survey national accreditation organizations, conduct validation surveys of accredited facilities, perform other surveys and activities, and make recommendations regarding the effective dates of provider dates of provider agreements and supplier approvals.[31]

On the basis of state survey agency recommendations, CMS will determine whether a provider or supplier is eligible to participate in or be covered under the Medicare program or an accredited hospital is deemed to meet the Medicare conditions of participation or is subject to full review by the state survey agency.[32]

The findings of a state agency regarding each of the conditions of participation, requirements for skilled-nursing facilities, or conditions for coverage must be adequately documented.[33]

iv. Periodic reviews to determine compliance

CMS may make determinations on whether a provider or supplier is complying with conditions of participation as often as CMS deems necessary, which may be more or less than a 12 month period.[34]

A state agency will certify that a provider or supplier is not in compliance with the conditions of participation or conditions for coverage: where the deficiencies substantially limit the provider's or supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients; or if CMS determines that an institution or agency does not qualify for participation or coverage because it is not in compliance with the conditions of participation or conditions for coverage.[35]

The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition.[36] A state survey agency must adhere to specific principles in determining compliance with participation requirements.

If a provider or supplier is found to be deficient with respect to one or more of the standards in the conditions of participation or conditions for coverage, it may participate in or be covered under the Health Insurance for the Aged and Disabled Program only if the facility has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the Secretary.[37]

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[31] 42 C.F.R. § 488.11
[32] 42 C.F.R. § 488.12
[33] 42 C.F.R. § 488.18
[34] 42 C.F.R. § 488.20
[35] 42 C.F.R. § 488.24
[36] 42 C.F.R. § 488.26
[37] 42 C.F.R. § 488.28

b) Special requirements

If a hospital is found to be out of compliance with one or more conditions of participation for hospitals, a temporary waiver may be granted by CMS.[38] CMS may extend a temporary waiver only if such a waiver would not jeopardize or adversely affect the health and safety of patients. The waiver may be withdrawn earlier if CMS determines this action is necessary to protect the health and safety of patients.

A skilled nursing facility may request its registered nurses to work more than 40 hours a week only in limited circumstances and based upon documented findings of a state agency. [39]

An end state renal disease facility and transplant centers that wishes to be approved for coverage must secure a determination by CMS.[40]

c) Reconsideration of adverse determinations, deeming authority for accreditation organizations and Clinical Laboratory Improvement Amendments ("CLIA") exemptions of laboratories under state programs

A skilled-nursing facility must undergo a survey process to assess whether the quality of care prescribed by regulations and needed by residents is actually being provided in nursing homes.[41] Facilities must continue to meet all applicable conditions and standards to participate in Medicare/Medicaid programs. The survey process will focus on resident outcomes and not solely on facility policies and procedures. Surveys must observe and interview residents in order to make that determination.

A national accreditation organization dissatisfied with a determination that its accreditation standards do not provide reasonable assurance that the entities accredited meet applicable long-term care requirements is entitled to a reconsideration.[42] A state dissatisfied with a determination that the requirements it imposes on laboratories do not provide reasonable assurance that laboratories meet CLIA requirements is entitled to a reconsideration.[43]

d) Survey and certification of long-term care facilities

Incentives and sanctions

A state may establish a program to reward nursing facilities ("NFs") that provide the highest quality care to Medicaid residents through public recognition or incentive payments.[44]

A state has the following powers against non-state operated NFs: termination of the provider agreement; temporary management; denial of payment for new admission; civil money penalties; transfer of residents; closure of the facility and transfer of residents; state monitoring;

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[38] 42 C.F.R. § 488.54
[39] 42 C.F.R. § 488.56
[40] 42 C.F.R. §§ 488.60; 488.61
[41] 42 C.F.R. § 488.110
[42] 42 C.F.R. § 488.201
[43] Id.
[44] 42 C.F.R. § 488.303

directed plan of correction; directed in-service training; and alternative or additional state remedies.[45]

State surveys

State survey agencies must comply with requirements for its standard surveys for each skilled nursing facility ("SNF") and NF.[46] All standard surveys must be unannounced.[47] An individual who notifies a SNF or NF of the time or date on which a standard survey is scheduled to be conducted may be penalized up to $2,000. The survey agency must conduct a standard survey of each SNF and NF every 15 months or more if necessary to determine a facility's compliance with participation requirements.[48]

The purpose of an extended survey is to identify the policies and procedures that caused the facility to furnish substandard quality of care.[49] The survey agency must conduct an extended survey not later than 14 calendar days after completion of a standard survey which found that the facility had furnished substandard quality of care.

CMS considers survey performance to be inadequate if the state survey agency: indicates a pattern of failure to identify deficiencies, cite only valid deficiencies, conduct surveys in accordance with regulatory requirements, or use federal standards specified by CMS; or fails to identify an immediate jeopardy situation.[50]

CMS assesses the performance of the state's survey and certification program annually. When a state demonstrates inadequate survey performance, CMS notifies the survey agency of the inadequacy and reduces federal financial participation (FFP) and provides training of survey teams.

A state survey agency surveys all facilities for compliance or noncompliance with requirements for long term care facilities.[51] The survey by the state survey agency may be followed by a federal validation survey. Regardless of the state entity doing the certification, its decision is final except on a complaint, a validation survey conducted by CMS, or CMS review of the state's findings. A facility may dispute survey findings upon the facility's receipt of the official statement of deficiencies.[52]

A state must conduct periodic educational programs for the staff and residents of SNFs and NFs to present current regulations, procedures, and policies on the survey, certification, and enforcement process.[53]

Public information

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[45] Id.
[46] 42 C.F.R. § 488.305
[47] 42 C.F.R. § 488.307
[48] 42 C.F.R. § 488.308
[49] 42 C.F.R. § 488.310
[50] 42 C.F.R. § 488.318
[51] 42 C.F.R. § 488.330
[52] 42 C.F.R. § 488.331
[53] 42 C.F.R. § 488.334

The following information must be made available to the public, upon the public's request, by the state or CMS for all surveys and certifications of SNFs and NFs: statements of deficiencies and providers' comments; a list of isolated deficiencies that constitute no actual harm, with the potential for minimal harm; approved plans of correction; statements that the facility did not submit an acceptable plan of correction or failed to comply with the conditions of imposed remedies; final appeal results; notice of termination of a facility; Medicare and Medicaid cost reports; names of individuals with direct or indirect ownership interest in a SNF or NF; and names of individuals with direct or indirect ownership interest in a SNF or NF who have been found guilty by a court of law of a criminal offense in violation of Medicare or Medicaid law. [54]

Complaints

A state survey agency must establish procedures and maintain adequate staff to investigate complaints of violations of participation requirements.[55] The state survey agency must take appropriate precautions to protect a complainant's anonymity and privacy. The state survey agency may conduct on-site monitoring when: a facility is not in substantial compliance with the requirements and is in the process of correcting deficiencies; a facility has corrected deficiencies and verification of continued substantial compliance is needed; or the survey agency has reason to question the substantial compliance of the facility with a requirement of participation.

A state must review all allegations of resident neglect and abuse and misappropriation of resident property.[56] The state must have written procedures for the timely review and investigation of allegations of resident abuse and neglect and misappropriation of resident property.

e) Enforcement of compliance for long-term care facilities with deficiencies

CMS or the state may sanction facilities to address noncompliance found during surveys.[57] In order to select the appropriate remedy to apply to a facility with deficiencies, CMS and the state must determine the seriousness of the deficiencies and consider other factors like the relationship of one deficiency to other deficiencies resulting in noncompliance and the facility's prior history of noncompliance.[58] In addition to termination of the provider agreement, the following remedies are available: temporary management; denial of Medicare/Medicaid payment; civil money penalties; state monitoring; transfer of residents; closure of the facility and transfer of residents; directed plan of correction; directed in-service training; and alternative or additional state remedies approved by CMS.[59] CMS or the state may deny Medicare or Medicaid payment for all new admissions or all residents when a facility is not in substantial compliance with requirements.[60]

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[54] 42 C.F.R. § 488.325
[55] 42 C.F.R. § 488.332
[56] 42 C.F.R. § 488.335
[57] 42 C.F.R. § 488.402
[58] 42 C.F.R. §§ 488.404; 488.408 through 488.414
[59] 42 C.F.R. § 488.406; 488.422 through 488.431; 488.456
[60] 42 C.F.R. § 488.417; 488.418

Each facility that has deficiencies must submit a plan of correction for approval by CMS or the survey agency.[61] A facility is not required to submit a plan of correction when it has deficiencies that are isolated and or has the potential for minimal harm.

CMS may continue payments to a facility not in substantial compliance if the state survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility, the state has submitted a plan and timetable for corrective action approved by CMS, and the facility agrees to repay the federal government payments received if corrective action is not taken in accordance with the approved plan and timetable for corrective action.[62]

f) Termination of Medicare coverage and alternative sanctions for end-stage renal disease ("ESRD") facilities

Failure of a supplier of ESRD services to meet one or more of the conditions for coverage will result in termination of Medicare coverage of the services furnished by the supplier.[63] CMS may, as an alternative to termination of Medicare coverage, impose one of the following sanctions: denial of payment for services furnished to patients; reduction of payments; and withholding of all payments.[64] CMS must give notice to a supplier and the general public of the alternative sanction and of the effective date of the sanction.[65] If CMS proposes to apply an alternative sanction, CMS must give the facility notice of the sanction and an opportunity to request a hearing.[66]

3) Hospitals

a) Basic Hospital Functions

Hospitals participating in Medicare must meet certain regulatory requirements.[67] The Secretary of the Department of Health and Human Services has the authority to impose additional requirements if they are necessary to protect patients' health and safety.[68]

Hospitals must comply with the following conditions of participation for Medicare:

- Hospitals must comply with applicable federal, state and local laws related to patient safety and licensing requirements.[69]
- A hospital must have a governing body legally responsible for the conduct of the hospital as an institution.[70]
- A hospital must protect and promote each patient's rights, including patients' visitation rights.[71]

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[61] 42 C.F.R. §§ 488.402; 488.424
[62] 42 C.F.R. § 488.450
[63] 42 C.F.R. § 488.604
[64] 42 C.F.R. § 488.606
[65] 42 C.F.R. § 488.608
[66] 42 C.F.R. § 488.610
[67] 42 C.F.R. § 482.1
[68] 42 C.F.R. § 482.1
[69] 42 C.F.R. § 482.11
[70] 42 C.F.R. § 482.12
[71] 42 C.F.R. §482.13

- The hospital must inform each patient or the patient's representative of the patient's rights prior to furnishing or discontinuing patient care. The hospital must establish a process for prompt resolution of patient grievances and inform each patient how to file a grievance.
- A hospital must develop a hospital-wide quality assessment and performance improvement program to improve health outcomes, identify and reduce medical errors, and measure quality indicators including adverse patient events.[72]
- A hospital must maintain a medical record for every patient.[73]
- A hospital must have a utilization review plan that provides for review of services furnished by the institution and its medical staff to patients entitled to benefits under the Medicare and Medicaid programs.[74]
- A hospital must have a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.[75]
- A hospital must have written protocols on organ procurement and transplantation.[76]

b) Optional Hospital Services

A hospital must provide the following services that meet the needs of patients and comply with acceptable standards of practice:

- Inpatient and outpatient surgical services[77]
- Anesthesia services[78]
- Nuclear medicine services[79]
- Outpatient services[80]
- Emergency services[81]
- Rehabilitation services[82]
- Respiratory care services[83]

c) Requirements for Specialty Hospitals

i. Psychiatric hospitals

Psychiatric hospitals must be primarily engaged in providing psychiatric services, meet the conditions of participation for hospitals, maintain clinical records on all patients and meet staffing requirements.[84] A patient's medical record must contain a psychiatric evaluation, a treatment plan, and the patient's progress.[85] A psychiatric hospital must have adequate

[72] 42 C.F.R. § 482.21
[73] 42 C.F.R. § 482.24
[74] 42 C.F.R. § 482.30
[75] 42 C.F.R. § 482.43
[76] 42 C.F.R. § 482.45
[77] 42 C.F.R. § 482.51
[78] 42 C.F.R. §482.52
[79] 42 C.F.R. §482.53
[80] 42 C.F.R. § 482.54
[81] 42 C.F.R. § 482.55
[82] 42 C.F.R. § 482.56
[83] 42 C.F.R. § 482.57
[84] 42 C.F.R. § 482.60
[85] 42 C.F.R. § 482.61

numbers of qualified professional and support staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.[86]

ii. Long-term care services

A hospital that has a Medicare provider agreement must meet several eligibility requirements in order to be granted CMS' approval to provide post-hospital extended care services and be reimbursed as a swing-bed hospital.[87] The facility must substantially comply with skilled nursing facility requirements.

iii. Transplant centers

A transplant center that has a Medicare provider agreement must meet the following conditions of participation in order to gain CMS' approval to provide transplant services:[88]

- A transplant center must be located in a transplant hospital that is a member of the Organ Procurement and Transplantation Network (OPTN).[89]
- A transplant center must notify CMS of any significant changes related to the center's transplant program or changes that could affect its compliance with the conditions of participation. [90]
- A transplant center must seek Medicare approval to provide transplantation services to pediatric patients.[91]
- Transplant centers must meet all data submission, clinical experience and outcome requirements to be granted initial approval and re-approval by CMS.[92]
- A transplant center must use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplantation.[93]
- Transplant centers must have written protocols for validation of donor-recipient blood type and other vital data for the decease organ recovery, organ receipt, and living donor organ transplantation processes.[94]
- Transplant centers must have written patient management policies for the transplant and discharge phases of transplantation.[95]
- Transplant centers must develop a written, comprehensive, data-driven quality assessment and performance improvement (QAPI) program designed to monitor and evaluate performance of all transplantation services including services provided under contract or arrangement.[96]

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[86] 42 C.F.R. § 482.62
[87] 42 C.F.R. § 482.66
[88] 42 C.F.R. §482.68
[89] 42 C.F.R. § 482.72
[90] 42 C.F.R. §482.74
[91] 42 C.F.R. §482.76
[92] 42 C.F.R. §§ 482.80; 482.82
[93] 42 C.F.R. § 482.90
[94] 42 C.F.R. § 482.92
[95] 42 C.F.R. § 482.94
[96] 42 C.F.R. § 482.96

- A transplant center must ensure that the hospital in which it operates has a written agreement for the receipt of organs with an organ procurement organization (OPO).[97]
- A transplant center must meet hospital's responsibilities to ensure patients' rights and protect and promote each transplant patient and living donor's rights.[98]
- Kidney transplant centers must directly furnish transplantation and other medical and surgical specialty services required for the care of end-stage renal disease patients. A kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.[99]

4) Long Term Care Facilities

a) Requirements for Long Term Care Facilities

Skilled nursing facilities and nursing facilities participating in Medicare must meet federal requirements for participation in the Medicare and Medicaid programs.[100]

A facility must be licensed under applicable state law and comply with federal and state laws.[101] The facility must have a governing body that is legally responsible for establishing policies regarding the management and operation of the facility. The facility must maintain clinical records on each resident. The facility must have detailed written plans and procedures related to potential emergencies and disasters. The facility must a written transfer agreement with one or more hospitals. A facility must maintain a quality assessment and assurance committee.

i. Residents' rights

A resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility.[102] A facility must protect and promote the rights of each resident. The facility must inform the resident of his or her rights both orally and in writing in a language that the resident understands.

A facility must permit each resident to remain in the facility unless the transfer or discharge is medically necessary, necessary to protect a resident's health and safety, the resident failed to pay for services, or the facility ceases to operate.[103] When the facility transfers or discharges a resident, it must be documented in the resident's clinical record. Before a facility transfers or discharges a resident, the facility must notify the resident and a family member or legal representative of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.

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[97] 42 C.F.R. §482.100
[98] 42 C.F.R. § 482.102
[99] 42 C.F.R. §482.104
[100] 42 C.F.R. § 483.1
[101] 42 C.F.R. § 483.75
[102] 42 C.F.R. § 483.10
[103] 42 C.F.R. §483.12

A facility must care for its residents in a manner and in an environment that promotes each resident's quality of life.[104] Each resident has the right to self-determination and participation, engage in activities, and care in a safe and clean environment.

ii. Long Term Care Facility Services

A facility must conduct initial and periodic assessments of each resident's functional capacity.[105] Each resident must receive the necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being.[106]

b) Preadmission Screening and Annual Resident Review (PASARR) of Mentally Ill and Mentally Retarded Individuals

The following regulatory requirements apply to the screening of all individuals with mental illness or mental retardation who apply to or reside in Medicaid certified nursing facilities.[107]

The states must operate preadmission screening and annual resident review (PASARR) programs as a condition of approval of the states' plan.[108] PASARR determinations made by state mental health or mental retardation authorities cannot be revoked by the state's Medicaid agency.[109] The PASARR must be coordinated with routine resident assessment to avoid duplicative testing and effort.

For each nursing facility applicant with mental illness or mental retardation, the state mental health or mental retardation authority must determine whether the individual requires the level of services provided by the nursing facility or requires specialized services.[110] For each resident of a nursing facility who has a mental illness or intellectual disability, state authorities must annually review whether the resident requires the level of services provided by the nursing facility and specialized services for mental illness or intellectual disability.[111] If the state mental health or mental retardation authority determines that a resident or applicant for admission to a NF requires a nursing facility level of services, the nursing facility may admit or retain the individual.[112] If the resident or applicant needs specialized services, then the state must provide or arrange for the provision of the specialized services needed by the individual while he resides in the nursing facility.[113] If state mental health or intellectual disability authority determines that an applicant for admission to a NF does not require NF services, the applicant cannot be admitted to a nursing facility. [114]

c) Resident Assessment

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[104] 42 C.F.R. § 483.15
[105] 42 C.F.R. §483.20
[106] 42 C.F.R. § 483.25
[107] 42 C.F.R. § 483.102
[108] 42 C.F.R. §§ 483.104; 483.106
[109] 42 C.F.R. § 483.108
[110] 42 C.F.R. §§ 483.112; 483.128 through 483.136
[111] 42 C.F.R. §§ 483.114; 483.128 through 483.136
[112] 42 C.F.R. §§ 483.116; 483.126
[113] 42 C.F.R. §§ 483.114; 483.120
[114] 42 C.F.R. § 483.118

States must specify the resident assessment instrument (RAI) that will be used by long-term care facilities when conducting initial and periodic assessments of each resident's function capacity.[115] The RAI must be approved by CMS.

d) The Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Residential Treatment Facilities for Individuals Under Age 21

A psychiatric residential treatment facility must meet regulatory requirements regarding the use of restraint or seclusion to patients under age 21.[116] Orders for restraint or seclusion must only be made by a physician permitted by a state and the facility.[117] If a physician orders restraint or seclusion, that person must contact the resident's treatment team physician and document in the resident's record the date and time the team physician was consulted.[118] Injuries must be documented in the resident's chart.[119] If the resident is a minor, the facility must notify the resident's parent(s) or legal guardian that the resident has been restrained or placed in seclusion as soon as possible after the initiation of each emergency safety intervention.[120]

Each psychiatric residential treatment facility that provides inpatient psychiatric services to individuals under age 21 must attest in writing that the facility is in compliance with CMS' standards governing the use of restraint and seclusion.[121] The facility must report each serious occurrence to both the state Medicaid agency and the state-designated protection and advocacy system. Serious occurrences include a resident's death, a serious injury, and a resident's suicide attempt.

e) Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

The Secretary of the Department of Health and Human Services has the authority to prescribe regulations for intermediate care facility services in facilities for the mentally retarded and related conditions.[122] Facilities must comply with other HHS regulations, including those pertaining to nondiscrimination requirements.[123] Violations of these regulations may result in the termination or suspension of federal financial assistance.

Intermediate care facilities must comply with the following conditions of participation:

- Facilities must have governing bodies, comply with applicable federal and state laws, protect client records, and have agreements with outside programs or services to provide for services not provided, including emergency and other health care.[124]

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[115] 42 C.F.R. § 483.315
[116] 42 C.F.R. § 483.354
[117] 42 C.F.R. § 483.358
[118] 42 C.F.R. § 483.360
[119] 42 C.F.R. § 483.372
[120] 42 C.F.R. § 483.366
[121] 42 C.F.R. § 483.374
[122] 42 C.F.R. § 483.400
[123] 42 C.F.R. § 483.405
[124] 42 C.F.R. § 483.410

- The facility must ensure the rights of all clients. Therefore, the facility must inform each client or the client's parent or legal guardian of the client's rights and the rules of the facility and of the client's medical condition, risks of treatment, and the right to refuse treatment. The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, or abuse of the client.[125]
- Each client's active treatment program must be coordinated and monitored by a qualified mental retardation professional. Each client must receive the professional program services needed to implement the active treatment program defined by the client's individual program plan.[126]
- Each client must receive a continuous active treatment program that is developed by an interdisciplinary team. Each facility must comply with standards related to admissions, transfers, and discharge. The client's progress must be documented in his or her records.[127]
- The facility must develop and implement written policies for the management of conduct between staff and clients and the management of inappropriate client behavior. [128]
- The facility must meet standards relating to physician services, physician participation in the individual program plan, nursing services, nursing staff, dental services, drug regimens, drug storage and recordkeeping, drug labeling, and laboratory services.[129]

5) Home Health Services

A home health agency must operate and furnish services in compliance with all applicable federal, state, and local laws and with accepted professional standards.[130] A home health agency must meet standards related to governance and services furnished.[131] A home health agency's operations must be annually reviewed by a group of professional personnel.[132] Home health agencies must meet standards related to plan of care, periodic review of plan of care, and conformance with physician orders.[133]

A home health agency must provide the following services by qualified professionals according to professional standards of care:

- Skilled nursing services[134]
- Any therapy services[135]
- Medical social services[136]
- Home health aide services[137]
- Outpatient physical therapy or speech pathology services[138]

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[125] 42 C.F.R. § 483.420
[126] 42 C.F.R. § 483.430
[127] 42 C.F.R. § 483.440
[128] 42 C.F.R. § 483.450
[129] 42 C.F.R. § 483.460
[130] 42 C.F.R. § 484.12
[131] 42 C.F.R. § 484.14
[132] 42 C.F.R. §§ 484.16; 484.52
[133] 42 C.F.R. § 484.18
[134] 42 C.F.R. § 484.30
[135] 42 C.F.R. § 484.32
[136] 42 C.F.R. § 484.34
[137] 42 C.F.R. § 484.36
[138] 42 C.F.R. § 484.38

A home health agency must provide each patient with a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes.[139] The assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the home health agency must verify the patient's eligibility for the Medicare home health benefit.

A home health agency must provide a patient with written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation before the initiation of treatment.[140] A home health agency must ensure the confidentiality of all patient identifiable information contained in the clinical record.[141] A home health agency must maintain clinical records for every patient, and they must be safeguarded against loss or unauthorized use.[142]

Home health agencies must electronically report all Outcome and Assessment Information Set (OASIS) data to the State agency or a CMS OASIS contractor.[143]

6) Certification of Certain Health Facilities

a) Rural health clinics and FQHCS

A rural health clinic (RHC) and federally qualified health center (FQHC) must comply with the following requirements in order to be certified for participation in Medicare:[144]

- A RHC must be located in a rural area that is designated in a shortage area.[145] A FQHC must be located in a rural or urban area that is designated as either a shortage area or an area that has a medically underserved population. Both the RHC and the FQHC may be permanent or mobile units.
- A RHC or FQHC must comply with requirements relating to construction, maintenance, and emergency procedures.[146]
- A RHC or FQHC must maintain a clinical record system. For each patient receiving health care services, the clinic or center must maintain a record in a manner that protects patient confidentiality.[147]
- A clinic or center must have an annual evaluation of its total program that reviews the utilization of its services, clinical records, and health care policies.[148]

7) Laboratory Requirements

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[139] 42 C.F.R. § 484.55
[140] 42 C.F.R. § 484.10
[141] 42 C.F.R. § 484.11
[142] 42 C.F.R. § 484.48
[143] 42 C.F.R. § 484.20
[144] 42 C.F.R. § 491.3
[145] 42 C.F.R. § 491.5
[146] 42 C.F.R. § 491.6
[147] 42 C.F.R. § 491.10
[148] 42 C.F.R. § 491.11

a) General

A laboratory must have a current certificate of waiver, registration certificate, certificate of compliance, certificate for Provider Performed Microscopy (PPM) procedures performed by the laboratory or be exempt.[149]

b) Registration certificate, certificate for provider-performed microscopy procedures, and certificate of compliance

Laboratories performing only waived tests, provider performed microscopy (PPM) procedures, or any combination of these tests is not required to obtain a registration certificate.[150] A registration certificate is required initially for all laboratories performing test procedures of moderate complexity or high complexity. HHS may suspend or revoke a laboratory's registration certificate for failure to comply with regulatory requirements.

Laboratories issued a certificate of compliance must notify HHS of any changes in ownership, name, location, director or technical supervisor.[151] The laboratory must also notify HHS if it performs any test that is not included in the laboratory's certificate of compliance.

c) Facility administration for nonwaived testing

Each laboratory that performs nonwaived testing must meet the following requirements unless HHS approves a procedure that provides equivalent quality testing.[152]

- A laboratory must be constructed, arranged and maintained to comply with federal, state, and local laboratory requirements.[153]
- A facility that provides transfusion services must meet all regulatory requirements and document transfusion-related activities.[154]
- A laboratory must retain its records and its slides, blocks, and tissues.[155]

d) Quality system for nonwaived testing

Each laboratory that performs nonwaived testing must establish written policies and procedures that implement and monitor a quality system for all phases of the total testing process and general laboratory systems.[156] The laboratory's quality systems must include a quality assessment component.

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[149] 42 C.F.R. § 493.3
[150] 42 C.F.R. § 493.45
[151] 42 C.F.R. § 493.51
[152] 42 C.F.R. § 493.1100
[153] 42 C.F.R. § 493.1101
[154] 42 C.F.R. § 493.1103
[155] 42 C.F.R. § 493.1101
[156] 42 C.F.R. §§ 493.1200; 493.1239

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements unless HHS approves a procedure that provides equivalent quality testing.[157]

- A laboratory must ensure confidentiality of patient information.[158]
- The laboratory must establish written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of receipt of the specimen through completion of testing and reporting of results.[159]
- A laboratory must have a system in place to ensure that it documents all complaints and problems reports to the laboratory.[160] It must conduct investigations of complaints when appropriate.
- A laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.[161]
- The laboratory must establish written policies and procedures to assess employee and consultant competency.
- A laboratory must review and evaluate the results obtained on proficiency testing performed.[162] All proficiency testing evaluation and verification activities must be documented.
- A written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to and followed by laboratory personnel.[163]
- Testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system.[164]

For each test system, a laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process, bacteriology tests, mycobacteriology tests, mycology tests, parasitology tests, virology tests, routine chemistry tests, hematology tests, immunohematology tests, histopathology tests, cytology tests, clinical cytogenetics, and histocompatibility tests .[165]

Corrective action policies and procedures must be followed to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.[166] The laboratory must document all corrective actions taken.

The laboratory must maintain an information or record system.[167] Records of patient testing must be retained.

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[157] 42 C.F.R. § 493.1230
[158] 42 C.F.R. § 493.1231
[159] 42 C.F.R. § 493.1232
[160] 42 C.F.R. § 493.1233
[161] 42 C.F.R. § 493.1234
[162] 42 C.F.R. § 493.1236
[163] 42 C.F.R. § 493.1251
[164] 42 C.F.R. § 493.1252
[165] 42 C.F.R. §§ 493.1256 to 493.1278
[166] 42 C.F.R. § 493.1282
[167] 42 C.F.R. § 493.1283

e) Enforcement procedures

CMS' decision to impose sanctions is based on deficiencies found by CMS in the conduct of inspections or through review of materials submitted by the laboratory and unsuccessful participation in proficiency testing.[168]

- CMS may impose one or more sanctions on a laboratory that is out of compliance with one or more CLIA conditions.[169]
- CMS may suspend, limit or revoke a CLIA certificate.[170] When CMS suspends or revokes any type of CLIA certificate, CMS must concurrently cancel the laboratory's approval to receive Medicare payment for its services.[171]
- CMS may also impose alternative sanctions: directed plan of correction; state onsite monitoring; and civil money penalty.[172]

CMS must cancel a laboratory's approval to receive Medicare payment for its services if CMS suspends or revoke its CLIA certificate.[173] It may also cancel the laboratory's approval if the laboratory is out of compliance with a condition level requirement, the laboratory fails to submit a satisfactory plan of correction, or the laboratory fails to correct all of its deficiencies within the time frames specified in the plan of correction.

If CMS identifies condition level noncompliance in a laboratory, CMS must provide the laboratory written notice and an opportunity to respond.[174] A laboratory may request a hearing with an administrative law judge or file a lawsuit in district court if it is dissatisfied with a CMS determination.[175]

If CMS has reason to believe that a laboratory's activities constitute a significant hazard to public health, CMS may bring suit in district court to stop the laboratory from continuing the activities.[176]

CMS must annually provide physicians and the general public information that is useful in evaluating the performance of laboratories.[177]

8) Coverage for End-Stage Renal Disease Facilities

a) General Provisions

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[168] 42 C.F.R. § 493.1804
[169] 42 C.F.R. § 493.1806
[170] 42 C.F.R. §§ 493.1806; 493.493.1807
[171] 42 C.F.R. § 493.1808
[172] 42 C.F.R. § 493.1806
[173] 42 C.F.R. § 493.1842
[174] 42 C.F.R. § 493.1810
[175] 42 C.F.R. § 493.1844
[176] 42 C.F.R. § 493.1846
[177] 42 C.F.R. § 493.1850

A dialysis facility and its staff must operate and furnish services in compliance with federal and state laws pertaining to licensure and other relevant health and safety requirements.[178]

b) Patient Safety

A dialysis facility must provide a sanitary environment to minimize the transmission of infectious diseases. [179] The facility must report incidences of communicable diseases as required by federal or state regulations.

A dialysis facility must be designed to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.[180] This regulation provides standards for the dialysis facility's building, patient care environment, emergency preparedness of staff, and fire safety.

c) Patient Care

A dialysis facility must inform patients or their representatives of their rights and responsibilities when they begin their treatment.[181] The facility must also display a copy of a list of patient's rights in the facility.

A dialysis facility's interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs.[182] The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

A dialysis facility must develop an effective, data-driven quality assessment and performance improvement program with participation by the interdisciplinary team.[183] The facility must maintain and demonstrate evidence of its quality and performance improvement program for review by CMS.

d) Administration

All dialysis staff must meet applicable licensure requirements and personnel qualifications.[184] A dialysis facility must have a medical director who is responsible for the delivery of patient care and outcomes in the facility.[185] The medical director must focus on quality assessment and performance improvement program and staff education and performance.

A dialysis facility must maintain records on all patients including home patients.[186] The facility must protect patient records, complete records in a prompt manner, keep information in a centeralized place, and retain patient records for 6 years from the date of the patient's discharge, transfer, or death.

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[178] 42 C.F.R. § 494.20
[179] 42 C.F.R. § 494.30
[180] 42 C.F.R. § 494.60
[181] 42 C.F.R. § 494.70
[182] 42 C.F.R. §§ 494.80; 494.90
[183] 42 C.F.R. § 494.110
[184] 42 C.F.R. § 494.140
[185] 42 C.F.R. § 494.150
[186] 42 C.F.R. § 494.170

9) Specialized Providers

a) Comprehensive outpatient rehabilitation facilities

Facilities must meet regulatory standards to be certified as comprehensive outpatient rehabilitation facilities (CORFs).[187] A CORF must comply with the following conditions of participation:

- A facility and its personnel must meet all applicable state and local laws, including licensure requirements.[188]
- A CORF must have a governing body that assumes full legal responsibility for establishing policies regarding the management and operation of the facility.[189]
- A CORF must provide a coordinated rehabilitation program that includes physicians' services, physical therapy services, and social or psychological services.[190]
- A facility must maintain clinical records on all patients and safeguard the records against loss or unauthorized use.[191]
- A facility must provide a physical environment that protects the health and safety of patients, personnel, and the public.[192]
- A facility must have written policies and procedures that defines the handling of patients, personnel, records, and the public during disasters.[193]
- A facility must have in effect a written utilization review plan that is implemented every 4 months to assess the necessity of services and promotes the most efficient use of services provided by the facility. A utilization review committee must carry out the utilization review plan.[194]
- A facility must comply with Medicare's appeal provisions for providers.[195]

b) Critical access hospitals

A rural health network is an organization that includes at least one critical access hospital (CAH) and at least one hospital that furnishes acute care services.[196] Critical access hospitals must hire clinical nurse specialists, nurse practitioners, and physician assistants who are licensed and completed a formal educational program.[197]

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[187] 42 C.F.R. § 485.50
[188] 42 C.F.R. § 485.54
[189] 42 C.F.R. § 485.56
[190] 42 C.F.R. § 485.58
[191] 42 C.F.R. § 485.60
[192] 42 C.F.R. § 485.62
[193] 42 C.F.R. § 485.64
[194] 42 C.F.R. § 485.66
[195] 42 C.F.R. § 485.74
[196] 42 C.F.R. § 485.603
[197] 42 C.F.R. § 485.604

A state that establishes a Medicare rural hospital flexibility program may designate one or more facilities as a critical access hospital if each facility meets the critical access hospital conditions of participation.[198] The conditions of participation include:

- A CAH and its staff must comply with applicable federal, state, and local laws.[199]
- A CAH must be a currently participating hospital and be located in a rural area or treat patients in a rural area.[200]
- A CAH must have a provider agreement to participate in the Medicare program.[201]
- A CAH must meet standards relating to agreements with network hospitals, agreements for credentialing and quality assurance, and agreements for credentialing and privileging of telemedicine physicians and practitioners.[202]
- A CAH must have a governing body that assumes full legal responsibility for determining policies governing the hospital's operation.[203]
- A CAH must maintain a clinical records system in a manner that ensures confidentiality.[204]
- If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners.[205]
- A CAH must meet standards relating to periodic evaluations of its program and quality assurance.[206]

c) Clinics, rehabilitations agencies, and public health agencies providing outpatient physical therapy and speech-language pathology services

A clinic, rehabilitation agency, and public health agencies providing outpatient physical therapy and speech-language pathology services must comply with the following conditions of participation:

- An organization and its staff must comply with federal, state, and local laws. The organization must comply with state licensure requirements.[207]
- A clinic or rehabilitation agency must have a governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. [208]
- A written plan of care must be established and periodically reviewed by a health care provider for each patient in need of outpatient physical therapy or speech pathology services.[209]
- An organization must maintain clinical records on all patients and must be safeguarded to protect patient confidentiality.[210]

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[198] 42 C.F.R. § 485.606
[199] 42 C.F.R. § 485.608
[200] 42 C.F.R. § 485.610
[201] 42 C.F.R. § 485.612
[202] 42 C.F.R. § 485.616
[203] 42 C.F.R. § 485.627
[204] 42 C.F.R. § 485.638
[205] 42 C.F.R. § 485.639
[206] 42 C.F.R. § 485.641
[207] 42 C.F.R. § 485.707
[208] 42 C.F.R. § 485.709
[209] 42 C.F.R. § 485.711
[210] 42 C.F.R. § 485.721

- An organization must have procedures that provide for a systematic evaluation of its total program to ensure appropriate utilization of services and to determine whether the organization's policies are followed in providing services to patients.[211]

10) Specialized Services Furnished by Suppliers

a) Organ Procurement Organizations

An organization procurement organization (OPO) is an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective beneficiaries for available organs.[212]

If an OPO wishes to terminate its agreement, it must send CMS written notice of its intent to terminate its agreement and the proposed effective date.[213] During the term of the agreement, CMS may terminate an agreement with an OPO if it no longer meets the requirements for certification. If an OPO's de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the decertification on substantive and procedural grounds.[214]

An OPO may be recertified if it complies with regulatory requirements.[215] There is a process of competition between OPOs if an OPO becomes decertified and its service area becomes open.

i. Conditions of coverage

An OPO must comply with the following conditions of coverage:

- An OPO must meet all outcome measures of organ donation.[216]
- An OPO must become a member of the Organ Procurement and Transplantation Network after becoming certified.[217]
- An OPO must have a written agreement with Medicare and Medicaid participating hospitals and critical access hospitals in its service area.[218] OPOs must also have arrangements to cooperate with tissue banks that have agreements with hospitals and critical access hospitals.
- An OPO must provide individually-identifiable, hospital-specific organ donation and transplantation data to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Beneficiaries, and the Department of Health and Human Services.[219]

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[211] 42 C.F.R. § 485.729
[212] 42 C.F.R. § 486.302
[213] 42 C.F.R. § 486.312
[214] 42 C.F.R. § 486.314
[215] 42 C.F.R. § 486.316
[216] 42 C.F.R. § 486.318
[217] 42 C.F.R. § 486.320
[218] 42 C.F.R. § 486.322
[219] 42 C.F.R. § 486.328

- An OPO must establish and use an electronic information management system to maintain the required medical, social and identifying information for every donor and transplant recipient and develop procedures to ensure the confidentiality and security of the information.[220]
- An OPO must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families.[221] An OPO must have a written protocol to ensure that the individual responsible for making the donation decision are informed of their options to donate organs or tissues or to decline to donate.
- The OPO must have written protocols for donor evaluation and management and organ placement and recovery that meet standards of practice and are designed to maximize organ quality and number of donors and organs.[222]
- An OPO must arrange for testing of organs for infectious disease and tissue typing of organs according to current standards of practice.[223]
- An OPO must develop a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all donation services.[224] An OPO's QAPI program must satisfy standards relating to the program's components, death record reviews, and adverse events.

[220] 42 C.F.R. § 486.330
[221] 42 C.F.R. § 486.342
[222] 42 C.F.R. § 486.344
[223] 42 C.F.R. § 486.346
[224] 42 C.F.R. § 486.348