

107TH CONGRESS
2^D SESSION

H. R. 5141

To amend title XVIII of the Social Security Act to direct the Secretary of Health and Human Services to establish a continuous quality improvement program for providers that furnish services under the Medicare Program to individuals with end stage renal disease, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 16, 2002

Mr. STARK introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to direct the Secretary of Health and Human Services to establish a continuous quality improvement program for providers that furnish services under the Medicare Program to individuals with end stage renal disease, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “ESRD Quality Im-
3 provement Act of 2002”.

4 **SEC. 2. CONTINUOUS QUALITY IMPROVEMENT PROGRAM**
5 **FOR ESRD FACILITIES UNDER MEDICARE.**

6 (a) IN GENERAL.—Section 1881 of the Social Secu-
7 rity Act (42 U.S.C. 1395rr) is amended by adding at the
8 end the following new subsection:

9 “(h) CONTINUOUS QUALITY IMPROVEMENT AND
10 QUALITY ASSURANCE PROGRAM.—

11 “(1) CQI AND QA PROGRAMS.—

12 “(A) IN GENERAL.—Not later than 1 year
13 after the date of the enactment of this sub-
14 section, the Secretary shall establish a manda-
15 tory continuous quality improvement program
16 (in this section referred to as the ‘CQI Pro-
17 gram’) and a mandatory quality assurance pro-
18 gram (in this section referred to as the ‘QA
19 Program’) for furnishing services to individuals
20 determined to have end stage renal disease
21 under this section. In establishing the CQI Pro-
22 gram and the QA Program, the Secretary shall
23 consult with representatives of patients, pro-
24 viders of services and renal dialysis facilities
25 (including facility administrators, physicians
26 (including nephrologists), dietitians, social

1 workers, and nurses), facilities, quality improve-
2 ment experts, and ESRD Network Administra-
3 tive Organizations (as defined in paragraph
4 (8)).

5 “(B) PROVISIONS RELATING TO QA PRO-
6 GRAM ONLY.—The Secretary shall contract with
7 the ESRD Network Administrative Organiza-
8 tions and with State survey agencies to conduct
9 a coordinated quality assurance program (in
10 this section referred to as the ‘QA Program’)
11 that recognizes excellent ESRD clinical out-
12 comes and imposes sanctions for chronically
13 substandard care.

14 “(C) COORDINATION WITH ESTABLISHED
15 DEPARTMENT OR ORGANIZATION PROGRAMS.—
16 The CQI Program required under this sub-
17 section, the ESRD Clinical Performance Meas-
18 ures required under paragraph (4), the infor-
19 mation management system required under
20 paragraph (5), the QA Program, and other
21 components of this subsection, as appropriate,
22 shall be established or developed in conjunction
23 with relevant quality improvement goals estab-
24 lished by the Secretary, or by ESRD Network
25 Administrative Organizations, which are in ef-

1 fect or in the process of development as of the
2 date of the enactment of this subsection.

3 “(2) DUTIES OF THE SECRETARY.—Under the
4 CQI Program the Secretary—

5 “(A) shall establish, and publish in the
6 Federal Register, the ESRD Clinical Perform-
7 ance Measures as described in paragraph (4);

8 “(B) shall collect and analyze data from
9 providers and facilities as described in para-
10 graph (5);

11 “(C) shall identify and reward outstanding
12 providers and facilities as described in para-
13 graph (6);

14 “(D) shall identify and provide for addi-
15 tional training to providers and facilities in
16 need of such training as described in paragraph
17 (7) and shall institute such disciplinary actions
18 as deemed appropriate against those providers
19 and facilities that fail to improve;

20 “(E) shall develop, in conjunction with the
21 Work Group, and implement a methodology to
22 identify serious medical errors and injuries in-
23 volving end-stage renal disease patients and to
24 analyze the causes for such injuries (such im-
25 plementation may first be initiated through a

1 demonstration project that is coordinated by
2 the ESRD Network Administrative Organiza-
3 tions);

4 “(F) delineate the shared and distinctive
5 duties of the ESRD Network Administrative
6 Organizations and State survey agencies with
7 respect to facility or provider certification and
8 investigation;

9 “(G) develop standards to evaluate the per-
10 formance of ESRD Network Administrative Or-
11 ganizations and State survey agencies; and

12 “(H) determine an appropriate uniform
13 minimum frequency for on-site dialysis certifi-
14 cation and recertification surveys.

15 “(3) DUTIES OF ESRD NETWORK ADMINIS-
16 TRATIVE ORGANIZATIONS.—ESRD Network Admin-
17 istrative Organizations shall perform the following
18 functions:

19 “(A) COLLECTION AND ANALYSIS OF DATA
20 ON PROCESSES AND OUTCOMES OF CARE; USE
21 OF ESRD CLINICAL PERFORMANCE MEAS-
22 URES.—

23 “(i) IN GENERAL.—The ESRD Net-
24 work Administrative Organizations shall
25 provide for the routine and timely data col-

1 lection, and statistical evaluation, of the
2 processes and outcomes of care for pa-
3 tients undergoing kidney transplant, hemo-
4 dialysis and other modalities requiring
5 blood access, and peritoneal dialysis.

6 “(ii) DATA USED.—In carrying out
7 such measurements and evaluations, the
8 ESRD Network Administrative Organiza-
9 tions shall use, among other data, the
10 ESRD Clinical Performance Measures es-
11 tablished under paragraph (4), and data
12 acquired under subparagraphs (F) and (H)
13 of subsection (c)(2), including medical in-
14 juries and their causes, medical errors, and
15 evidence of Hepatitis B and C serologic
16 conversion of patients or staff.

17 “(iii) FEEDBACK TO PROVIDERS AND
18 FACILITIES.—The ESRD Network Admin-
19 istrative Organizations shall provide feed-
20 back to providers, facilities, and physi-
21 cians, from whom data has been collected
22 of their patterns of practice and ESRD
23 Clinical Performance Measures outcomes
24 as compared to the following:

1 “(I) National averages of such
2 patterns and outcomes.

3 “(II) State, Network, and where
4 statistically appropriate, local aver-
5 ages of such patterns and outcomes.

6 “(III) Clinical goals established
7 by the Secretary of such patterns and
8 outcomes.

9 “(B) DISSEMINATION OF RECOMMENDED
10 CLINICAL PRACTICES.—The ESRD Network
11 Administrative Organizations shall disseminate
12 recommended clinical practices derived from
13 evidence based practice guidelines or clinical al-
14 gorithms to medical directors of dialysis facili-
15 ties and to such other providers of services as
16 the Secretary determines appropriate.

17 “(C) MONITORING PATIENT AND STAFF
18 SATISFACTION.—The ESRD Network Adminis-
19 trative Organizations, individual renal dialysis
20 facilities, and individual providers of services
21 shall collaborate to develop a uniform
22 mechanism—

23 “(i) to monitor patient and staff satis-
24 faction and shall ensure an effective and
25 integrated complaint system; and

1 “(ii) for the reporting of data by di-
2 alysis facility to the Network of the nurse
3 to patient ratio and the technician to pa-
4 tient ratio of the facility.

5 State survey agencies shall also collaborate in
6 the establishment of the mechanism with re-
7 spect to clause (i).

8 “(D) PEER REVIEW.—The ESRD Network
9 Administrative Organizations shall conduct re-
10 gional and national peer review of renal dialysis
11 facilities and providers of services.

12 “(E) TECHNICAL ASSISTANCE.—The
13 ESRD Network Administrative Organizations
14 shall provide technical assistance for quality im-
15 provement efforts and identify quality improve-
16 ment activities to reflect evolving needs of facili-
17 ties and patients including rehabilitation, pa-
18 tient education, community outreach, grievance
19 resolution, and patient rights and responsibil-
20 ities.

21 “(F) GUIDANCE ON COLLECTION AND CAL-
22 CULATION OF CLINICAL PERFORMANCE MEAS-
23 URES.—In consultation with the Work Group
24 (as defined in paragraph (8), the ESRD Net-
25 work Administrative Organizations shall provide

1 guidance to providers of services and renal di-
2 alysis facilities on the collection and measure-
3 ment of the ESRD Clinical Performance Meas-
4 ures.

5 “(G) DISSEMINATION OF INFORMATION ON
6 CQI PROGRAM AND QA PROGRAM.—

7 “(i) IN GENERAL.—The ESRD Net-
8 work Administrative Organizations shall
9 make information and materials under the
10 program available for the use of—

11 “(I) facilities and providers in
12 Medicare+Choice organizations;

13 “(II) facilities and providers that
14 do not receive payments under this
15 title;

16 “(III) private payers of services
17 for end stage renal disease patients;
18 and

19 “(IV) end stage renal disease pa-
20 tients and families.

21 “(ii) REQUIREMENTS RELATING TO
22 PATIENT INFORMATION.—

23 “(I) IN GENERAL.—In making
24 available information under clause (i)
25 for patients and families, the ESRD

1 Network Administrative Organizations
2 shall make available the information
3 described in subclause (II) in printed
4 and electronic format. The content of
5 such information shall be determined
6 by the Work Group.

7 “(II) INFORMATION DE-
8 SCRIBED.—The information referred
9 to in subclause (I) is CQI Program in-
10 formation and facility-specific ESRD
11 Clinical Performance measures and
12 outcomes, including comparisons to
13 clinical goals established by the Sec-
14 retary under subparagraph
15 (A)(iii)(III) and national and appro-
16 priate State, Network, and local aver-
17 ages of such measures and outcomes.

18 “(4) ESRD CLINICAL PERFORMANCE MEAS-
19 URES.—

20 “(A) DEVELOPMENT OF INITIAL INDICA-
21 TORS.—Not later than 1 year after the date of
22 the enactment of this subsection, the Work
23 Group as defined in paragraph (8), shall define
24 a set of ESRD Clinical Performance Measures.

1 “(B) UPDATING OF INDICATORS.—The
2 Work Group shall periodically update the
3 ESRD Clinical Performance Measures defined
4 in subparagraph (A).

5 “(C) AUTHORITY TO CONSIDER CERTAIN
6 INDICATORS.—The ESRD Clinical Performance
7 Measures defined under subparagraph (A) and
8 updated under subparagraph (B) may include
9 patient outcome measures based upon the fol-
10 lowing types of indicators:

11 “(i) Adequacy of hemodialysis and
12 peritoneal dialysis.

13 “(ii) Adequacy of nutrition including
14 bone and mineral metabolism.

15 “(iii) Vascular access.

16 “(iv) Anemia management including
17 average per patient dosage of anti-anemia
18 medications.

19 “(v) Standardized mortality ratios.

20 “(vi) Standardized hospitalization ra-
21 tios and average length of hospital stay.

22 “(vii) Standardized transplantation
23 ratios.

24 “(viii) Adequacy of blood pressure
25 control.

1 “(ix) Successful vocational mainte-
2 nance or rehabilitation.

3 “(x) Referral for self-treatment at
4 home.

5 “(xi) Appropriate administration of
6 clinical laboratory tests.

7 “(xii) Such other indicators as the
8 Work Group considers appropriate, includ-
9 ing any appropriate unique measures for
10 kidney transplant centers.

11 “(D) COORDINATION WITH ESTABLISHED
12 DEPARTMENT OR ORGANIZATION QUALITY IM-
13 PROVEMENT GOALS.—To the greatest extent
14 possible, the ESRD Clinical Performance Meas-
15 ures shall be defined in conjunction with rel-
16 evant quality improvement goals established by
17 the Secretary, or by ESRD Network Adminis-
18 trative Organizations, which are in effect or in
19 the process of development as of the date of the
20 enactment of this paragraph, including informa-
21 tion system design and implementation, and en-
22 hanced data collection, analysis, and reporting
23 initiatives.

24 “(E) AUTHORITY FOR ORGANIZATIONS TO
25 ESTABLISH CERTAIN SPECIFIC INDICATORS.—

1 The ESRD Network Administrative Organiza-
2 tions, individual renal dialysis facilities, and in-
3 dividual providers of services may establish ad-
4 ditional independent patient-specific, physician-
5 specific or facility-specific performance meas-
6 ures.

7 “(F) PUBLICATION IN THE FEDERAL REG-
8 ISTER.—The Secretary shall publish in the Fed-
9 eral Register the ESRD Clinical Performance
10 Measures as defined under subparagraph (A),
11 and as updated in subparagraph (B).

12 “(5) ESRD CQI PROGRAM.—

13 “(A) INFORMATION MANAGEMENT SYS-
14 TEM.—Not later than 2 years after the date of
15 the enactment of this subsection, the Secretary
16 shall establish an information management sys-
17 tem. The purpose of the information manage-
18 ment system is to provide for the electronic
19 transfer of data obtained under the CQI Pro-
20 gram and the QA Program among providers of
21 services, renal dialysis facilities, the Secretary,
22 ESRD Network Administrative Organizations,
23 and state agencies under contract with the Sec-
24 retary to conduct surveys of dialysis facilities.
25 The Secretary shall provide for technical assist-

1 ance in the use of the information management
2 system and for the development (or purchase)
3 and distribution of appropriate electronic soft-
4 ware for access to the information management
5 system.

6 “(B) MANNER OF USE OF INFORMATION
7 MANAGEMENT SYSTEM.—

8 “(i) PROVIDERS OF SERVICES AND
9 FACILITIES.—Each provider of services
10 and each renal dialysis facility shall con-
11 tribute data obtained under the CQI Pro-
12 gram and the QA Program to the informa-
13 tion management system.

14 “(ii) ESRD NETWORK ADMINISTRA-
15 TIVE ORGANIZATIONS.—Each ESRD Net-
16 work Administrative Organization shall
17 generate clinical profiles on the perform-
18 ance of renal dialysis facilities and indi-
19 vidual providers of services, and shall mon-
20 itor trends relevant to performance of fa-
21 cilities and providers.

22 “(C) DUTIES OF THE SECRETARY.—With
23 respect to data contributed to the information
24 management system, the Secretary shall per-
25 form the following duties:

1 “(i) COLLECTION OF UNADJUSTED
2 DATA.—The Secretary shall use the infor-
3 mation management system to collect, at
4 least biannually, the unadjusted data re-
5 quired to compute standards on all patient
6 outcomes—

7 “(I) from each provider of serv-
8 ices and renal dialysis facility; and

9 “(II) from physicians providing
10 services to individuals determined to
11 have end stage renal disease under
12 this section.

13 “(ii) COMPILATION OF DATA.—The
14 Secretary shall combine the data collected
15 under clause (i) on individual patient out-
16 comes into aggregate data for each pro-
17 vider of services and renal dialysis facility
18 and for each such physician.

19 “(iii) RISK-ADJUSTED COMPARISONS
20 OF PROVIDERS.—To the extent possible,
21 the Secretary shall adjust the data com-
22 bined under clause (ii) to establish risk ad-
23 justed comparisons of the ESRD Clinical
24 Performance Measures of—

1 “(I) each provider of services and
2 renal dialysis facility with other such
3 providers and facilities;

4 “(II) each such physician with
5 other such physicians in the network
6 area and the nation; and

7 “(III) the current clinical out-
8 come goals established by the Sec-
9 retary (as periodically updated).

10 “(iv) NATIONAL CLINICAL PERFORM-
11 ANCE MEASURES DATABASE.—The Sec-
12 retary shall administer a national clinical
13 performance measures database from the
14 data combined and adjusted under this
15 subparagraph.

16 “(v) CONFIDENTIAL REPORTS.—
17 Using CQI reports that preserve patient
18 confidentiality and confidentiality between
19 providers and facilities, the Secretary shall
20 report—

21 “(I) each provider’s and facility’s
22 combined and adjusted data under
23 this subparagraph to the provider or
24 facility and each such physician’s

1 combined and adjusted data under
2 this subparagraph to the physician;

3 “(II) how that provider, facility,
4 and physician (as the case may be)
5 compare in various CQI indicators to
6 other providers, facilities, or physi-
7 cians in the same network, in all net-
8 works, and to the ESRD Clinical Per-
9 formance Measures; and

10 “(III) such data to the ESRD
11 Network Administrative Organization
12 for the network area in which the pro-
13 vider, facility or physician is located.

14 “(vi) DISSEMINATION OF CERTAIN
15 DATA.—While protecting patient, provider,
16 and facility confidentiality, the Secretary
17 shall provide the data collected under
18 clauses (i), (ii), and (iii) to the United
19 States Renal Data System, State survey
20 agencies, and other public entities that the
21 Secretary determines is engaged in efforts
22 to improve the quality of services for renal
23 patients.

24 “(D) REQUIREMENT TO REPORT DATA ON
25 PATIENTS DISCHARGED FOR NONCOMPLIANCE

1 WITH TREATMENT PLAN.—In the case of an in-
2 dividual who is discharged from a facility or
3 provider by the facility, provider, or a physician,
4 for noncompliance with the treatment plan es-
5 tablished for the individual by the facility, pro-
6 vider, or physician, as the case may be, the fa-
7 cility, provider, or physician shall report such
8 discharge and reasons for the discharge to the
9 Secretary.

10 “(E) PLAN TO IMPROVE SERVICES.—In
11 the case of a facility notified under paragraph
12 (7)(B), the ESRD Network Administrative Or-
13 ganization for the network area in which the fa-
14 cility is located, in conjunction with the facility,
15 shall develop strategies to improve the provision
16 of services at the facility and shall provide ap-
17 propriate training in CQI Program processes to
18 the facility.

19 “(F) PHYSICIAN TRAINING.—The ESRD
20 Network Administrative Organization for the
21 network area in which the facility is located, in
22 conjunction with the facility, shall review the
23 quality of service provided by physicians noti-
24 fied under paragraph (7)(B) or identified under
25 subparagraph (E) at such facility for the pur-

1 poses of identifying those physicians that re-
2 quire training in CQI Program processes. In
3 the case of a physician notified under para-
4 graph (7)(B) or identified under subparagraph
5 (E), the ESRD Network Administrative Orga-
6 nization for the area in which the physician is
7 located, in conjunction with the physician, shall
8 develop strategies to improve the provision of
9 services by the physician, and shall provide ap-
10 propriate training in CQI Program processes to
11 the physician.

12 “(6) AWARDS FOR OUTSTANDING PROVIDERS
13 AND FACILITIES.—

14 “(A) DESIGNATION OF FACILITY OR PHY-
15 SICIAN AS A MEDICARE DIALYSIS PROVIDER OF
16 ACHIEVEMENT.—For each of 2005, 2006, and
17 2007, the Secretary shall designate Medicare
18 Dialysis Providers of Achievement (as defined
19 in subparagraph (B)).

20 “(B) DEFINITION OF MEDICARE DIALYSIS
21 PROVIDER OF ACHIEVEMENT.—A Medicare Di-
22 alysis Provider of Achievement is a renal dialy-
23 sis facility, or a physician, identified by the Sec-
24 retary as being 2 standard deviations above the
25 national norm for a preponderance of ESRD

1 Clinical Performance Measures on a case sever-
2 ity-risk adjusted basis for 2 consecutive report-
3 ing periods (covering in the aggregate a period
4 of at least 1 year).

5 “(C) AUTHORITY TO MAKE BONUS PAY-
6 MENTS.—The Secretary may make a payment
7 to a Medicare Dialysis Provider of
8 Achievement—

9 “(i) in a single monetary payment of
10 not less than \$1,000 and not greater than
11 to \$5,000; or

12 “(ii) by increasing the reimbursement
13 rate otherwise applicable under this section
14 to the facility or physician by 1 to 3 per-
15 cent for a period of 1 year.

16 “(D) REPORT ON SUCCESSFUL PROCESSES
17 AND TECHNIQUES.—Upon request by any
18 ESRD Network Administrative Organization, a
19 Medicare Dialysis Provider of Achievement des-
20 ignated under subparagraph (A) shall submit to
21 such organization a report on the clinical proc-
22 ess and monitoring techniques which the facility
23 determines are most responsible for the facili-
24 ty’s or physician’s successful outcomes for use
25 as a model for other facilities and physicians.

1 “(E) LIST OF MEDICARE DIALYSIS PRO-
2 VIDERS OF ACHIEVEMENT.—The Secretary
3 shall maintain and update a list of Medicare
4 Dialysis Providers of Achievement. Not later
5 than March 1 of each of 2006, 2007, and 2008,
6 the Secretary shall publish such list for the ap-
7 plicable preceding year in the Federal Register.
8 The appropriate ESRD Network Administrative
9 Organization shall publicly recognize such pro-
10 viders of achievement at an annual meeting.

11 “(7) ESRD QA PROGRAM.—

12 “(A) REVIEW OF CQI DATA TO IDENTIFY
13 CHRONICALLY SUBSTANDARD PROVIDERS.—

14 “(i) IN GENERAL.—The ESRD Net-
15 work Administrative Organizations shall
16 review the quantitative, evidence-based
17 ESRD Clinical Performance Measures to
18 identify chronically substandard facilities,
19 providers, and physicians.

20 “(ii) USE OF DATA.—Data identified
21 by the ESRD Network Administrative Or-
22 ganizations under clause (i) shall be sub-
23 mitted to the appropriate State survey
24 agency to initiate review and appropriate
25 subsequent actions. Such actions shall be

1 coordinated with the appropriate ESRD
2 Network Administrative Organization.

3 “(B) NOTICE OF SUBSTANDARD SERV-
4 ICES.—If the Secretary or the ESRD Network
5 Administrative Organization for the network
6 area in which a dialysis facility or physician is
7 located determines that the facility or physician
8 is 2 standard deviations below the national
9 norm for a preponderance of the ESRD Clinical
10 Performance Measures selected for this purpose
11 by the Work Group on a case severity-risk ad-
12 justed basis for 2 consecutive reporting periods
13 (covering in the aggregate a period of at least
14 1 year), the Secretary or ESRD Network Ad-
15 ministrative Organization shall notify the facili-
16 ty’s medical director and any affected attending
17 physicians of such determination.

18 “(C) SANCTIONS FOR ESRD NETWORKS.—
19 If the Secretary finds that an ESRD Network
20 Administrative Organization has not made a
21 good faith effort to carry out all of the data col-
22 lection, CQI Program, QA Program, adminis-
23 trative and oversight activities assigned, the
24 Secretary may—

1 “(i) require within a specified time
2 frame, a plan of correction; and

3 “(ii) terminate any contracts with the
4 ESRD Network Administrative Organiza-
5 tion and reshape the networks by merging
6 or otherwise redefining the geographic
7 areas of responsibility.

8 “(D) SANCTIONS FOR FACILITIES.—If the
9 Secretary finds that the facility or medical di-
10 rector has not made a good faith effort to im-
11 prove its performance under this paragraph, the
12 Secretary shall—

13 “(i) subject to subparagraph (F)—

14 “(I) assess a civil monetary pen-
15 alty of not less than \$500 and not
16 more than \$10,000;

17 “(II) reduce reimbursement rates
18 under this section by not less than 1
19 and not more than 3 percent for a pe-
20 riod not to exceed one year, or

21 “(III) in the event of life-threat-
22 ening or recurrent violations, termi-
23 nate or withhold certification of the
24 facility for purposes of payment under
25 this section; and

1 “(ii) notify and work collaboratively
2 with the ESRD Network Administrative
3 Organization involved and appropriate
4 State survey agency to carry out (if appro-
5 priate) one or more of the following ac-
6 tions:

7 “(I) Recommend that a sub-
8 stitute administrator or director be
9 appointed by the appropriate State
10 agency or officer with the authority to
11 hire, terminate and reassign staff, ob-
12 ligate funds, and alter facility proce-
13 dures as appropriate.

14 “(II) Require corrective action
15 within specified time frames according
16 to a plan developed by the network,
17 the State, or the temporary manager
18 (if any is appointed).

19 “(III) Place an on-site monitor to
20 ensure the facility achieves and main-
21 tains acceptable levels of quality in
22 furnishing services.

23 “(IV) Carry out such other ac-
24 tions as the Secretary determines ap-
25 propriate.

1 “(E) SANCTIONS FOR PHYSICIANS.—If the
2 Secretary finds that the attending physician has
3 not made a good faith effort to improve per-
4 formance under this paragraph, the Secretary
5 shall initiate—

6 “(i) further investigation of the physi-
7 cian; or

8 “(ii) such other actions as the Sec-
9 retary determines appropriate, after con-
10 sultation with the appropriate ESRD Net-
11 work Administrative Organization and
12 State survey agency.

13 “(F) DETERMINATION OF RESPONSIBILITY
14 FOR SUBSTANDARD SERVICES.—If the Sec-
15 retary terminates or withholds the certification
16 of a facility under subparagraph (D)(i)(III), the
17 State survey organization and the ESRD Net-
18 work Administrative Organizations involved
19 shall submit to the Secretary a statement with
20 respect to the relative responsibility of the facil-
21 ity, the medical director, and attending physi-
22 cian for the deficiencies involved.

23 “(8) DEFINITIONS.—As used in this subsection:

24 “(A) ESRD NETWORK ADMINISTRATIVE
25 ORGANIZATION.—The term ‘ESRD Network

1 Administrative Organization’ means a network
2 administrative organization designated under
3 subsection (c)(1)(A)(i)(II).

4 “(B) WORK GROUP.—The term ‘Work
5 Group’ means the ESRD Clinical Performance
6 Measures Work Group established under this
7 subparagraph as follows:

8 “(i) COMPOSITION.—The Work Group
9 shall be composed of the Secretary and of
10 such representatives of patient advocacy
11 groups, providers of renal services, the net-
12 work administrative organizations, the
13 United States Renal Data System, patient
14 vocational and rehabilitation organizations,
15 and quality improvement organizations
16 that the Secretary appoints.

17 “(ii) TERM.—Members of the Work
18 Group who are appointed by the Secretary
19 may not serve for more than three con-
20 secutive terms.

21 “(iii) APPLICATION OF FACA.—The
22 provisions of the Federal Advisory Com-
23 mittee Act (5 U.S.C. App.), other than sec-
24 tion 14(a)(2)(B) of such Act (relating to

1 the termination of advisory committees),
2 shall apply to the Work Group.”.

3 (b) RESPONSIBILITIES OF ESRD PROVIDERS, FA-
4 CILITIES, NETWORKS AND STATE SURVEY AGENCIES.—

5 (1) PARTICIPATION IN CQI PROGRAM AND QA
6 PROGRAM AS REQUIREMENT FOR MEDICARE PAY-
7 MENT FOR PROVIDERS AND FACILITIES.—

8 (A) IN GENERAL.—The second sentence of
9 section 1881(b)(1) of the Social Security Act
10 (42 U.S.C. 1395rr(b)(1)) is amended by insert-
11 ing before the period the following: “, and a re-
12 quirement that the provider of services or renal
13 dialysis facility meet the requirements of sub-
14 section (i) with respect to participation in the
15 CQI Program and the QA Program under sub-
16 section (h)”.

17 (B) SPECIFIC REQUIREMENTS DE-
18 SCRIBED.—Section 1881 of such Act (42
19 U.S.C. 1395rr), as amended by subsection a, is
20 amended by adding at the end the following
21 new subsection:

22 “(i) MANDATORY PARTICIPATION IN CQI PRO-
23 GRAM.—

24 “(1) IN GENERAL.—For purposes of subsection
25 (b)(1), each provider of services or renal dialysis fa-

1 cility shall take such actions as may be required for
2 the provider or facility to participate in the CQI
3 Program and the QA Program under subsection (h),
4 including—

5 “(A) establishing a CQI team (as defined
6 in paragraph (3));

7 “(B) developing and operating a quality
8 improvement program consistent with the re-
9 quirements of the CQI Program under sub-
10 section (h);

11 “(C) furnishing information required for
12 the collection and reporting of data under sub-
13 section (h)(4);

14 “(D) posting in a prominent location of the
15 provider or facility the data described in sub-
16 section (h)(3)(A)(ii); and

17 “(E) taking any other action which the
18 Secretary or the ESRD Network Administrative
19 Organizations may require in the administra-
20 tion of the CQI Program or the QA Program.

21 “(2) SANCTIONS FOR REPORTING FALSE
22 DATA.—If the Secretary determines that a facility or
23 provider has knowingly and willfully reported false
24 data under the CQI Program or the QA Program,
25 the Secretary shall terminate certification of the fa-

1 cility or provider for the purposes of payment for
2 services furnished to individuals with end stage renal
3 disease and shall ensure the placement of the facili-
4 ty's patients with another qualified provider.

5 “(3) DEFINITION OF CQI TEAM.—The term
6 ‘CQI team’ means a group established by a provider
7 of services or renal dialysis facility as follows:

8 “(A) COMPOSITION.—

9 “(i) IN GENERAL.—The group shall
10 consist of the medical director, director of
11 nursing, social worker, dietitian, and chief
12 technician of the provider or facility, and
13 shall include representatives of the patients
14 of the provider or facility.

15 “(ii) DIRECTOR.—The group shall
16 designate one of its members as the Direc-
17 tor of Continuous Quality Improvement for
18 the provider or facility who shall coordi-
19 nate with the ESRD Network Administra-
20 tive Organization for the network area in
21 which the provider or facility is located on
22 CQI Program issues.

23 “(B) DUTIES.—The group shall—

1 “(i) ensure that the provider or facil-
2 ity meets the requirements of this para-
3 graph;

4 “(ii) consistent with the standards of
5 the CQI Program under subsection (h),
6 promote clinical practice guidelines or algo-
7 rithms for the use of the provider or facil-
8 ity; and

9 “(iii) take any other actions which
10 may be required to ensure the full partici-
11 pation of the provider or facility in the
12 CQI Program under subsection (h).

13 “(C) MEETINGS.—The group shall periodi-
14 cally hold meetings, which shall be open to pa-
15 tients and personnel of the provider or facility,
16 and make minutes of the meetings available to
17 patients and personnel for a reasonable period
18 of time.”.

19 (2) RESPONSIBILITIES OF ESRD NETWORK AD-
20 MINISTRATIVE ORGANIZATIONS.—

21 (A) ASSISTANCE IN OPERATION OF PRO-
22 GRAM.—Section 1881(e)(2)(B) of such Act (42
23 U.S.C. 1395rr(e)(2)(B)) is amended by insert-
24 ing after “(B)” the following: “assisting the
25 Secretary in the administration of the CQI Pro-

1 gram under subsection (h) and (consistent with
2 the operation of such Program)”.

3 (B) COLLECTION AND DISSEMINATION OF
4 CQI DATA.—Section 1881(c)(2) of such Act (42
5 U.S.C. 1395rr (c)(2)) is amended—

6 (i) by striking “and” at the end of
7 subparagraph (G);

8 (ii) by redesignating subparagraph
9 (H) as subparagraph (I); and

10 (iii) by inserting after subparagraph
11 (G) the following new subparagraph:

12 “(H) collecting and making public data on fa-
13 cilities and providers generated under the CQI Pro-
14 gram under subsection (h) (in accordance with
15 standards established by the Secretary in consulta-
16 tion with representatives of providers, facilities, and
17 patients) and auditing samples of such data to en-
18 sure its accuracy.”.

19 (3) RESPONSIBILITIES OF STATE SURVEY
20 AGENCIES.—Section 1881, as amended by sub-
21 section (a) and paragraph (1)(B), is further amend-
22 ed by adding at the end the following new sub-
23 section:

24 “(j) ASSISTANCE OF STATE SURVEY AGENCIES.—
25 Each State agency responsible for the licensing of a pro-

1 vider or facility shall provide the following assistance
2 under this section:

3 “(1) ASSISTANCE IN OPERATION OF PRO-
4 GRAM.—The State agency shall provide such assist-
5 ance to the Secretary and the ESRD Network Ad-
6 ministrative Organizations in the administration of
7 the CQI Program and the QA Program under sub-
8 section (h) and (consistent with the operation of
9 such Program) as the Secretary requires.

10 “(2) COLLECTION AND DISSEMINATION OF CQI
11 DATA.—The State agency shall forward copies of all
12 complaints, investigations and surveys of providers
13 or facilities to the appropriate ESRD Network Ad-
14 ministrative Organizations.”.

15 (4) EFFECTIVE DATE.—The amendments made
16 by this subsection shall apply to services furnished
17 on or after the date that is one year after the date
18 of the enactment of this Act.

19 (c) PAYMENTS OF DIALYSIS USER FEES FOR ALL
20 DIALYSIS PERFORMED.—

21 (1) IN GENERAL.—The seventh sentence of sec-
22 tion 1881(b)(7) of the Social Security Act (42
23 U.S.C. 1395rr(b)(7)) is amended by inserting after
24 “50 cents” the following: “(and in the case of each
25 treatment furnished to individuals during the 30-

1 month period during which section 1862(b)(1)(C)
2 applies, the Secretary shall pay 50 cents)''.

3 (2) EFFECTIVE DATE.—The amendment made
4 by paragraph (1) shall apply to services furnished on
5 or after the date of the enactment of this Act.

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