

CODE OF D.C. MUNICIPAL REGULATIONS

TITLE 22. PUBLIC HEALTH AND MEDICINE

CHAPTER 40 CERTIFICATES OF NEED

CHAPTER 41 CERTIFICATE OF NEED REVIEW

CHAPTER 42 APPLICATION FOR CERTIFICATE OF NEED REVIEW

CHAPTER 43 REVIEW SCHEDULES

CHAPTER 44 UNCOMPENSATED CARE

CHAPTER 45 DATA REPORTING

Title 22-B DCMR (Public Health & Medicine) is amended by repealing Chapter 46, striking Chapters 40 through 43 and 45 in their entirety, and inserting new Chapters 40 through 43 and 45 to read as follows:

CHAPTER 40 CERTIFICATES OF NEED

4000 GENERAL PROVISIONS

- 4000.1 The provisions of Chapters 40 through 45 shall apply to a review of an application for a Certificate of Need (CON) required under Section 7 of the District of Columbia Health Services Planning Program Re-Establishment Act of 1996 as amended (Act), effective April 9, 1997 (D.C. Law 11-191; D.C. Official Code § 44-406).
- 4000.2 No person shall undertake any activity for which a CON is required if:
- (a) The original term of the CON has expired and the person has not obtained an extension pursuant to Section 4007; or
 - (b) The Director has revoked the CON pursuant to Section 4010 or Section 4308 of this title.
- 4000.3 A CON shall be valid for up to three (3) years.
- 4000.4 A CON shall be valid upon its issuance. However, because the Director may revoke or modify a CON after reconsideration or an appeal decision, a CON holder proceeds solely at its own risk during the period when reconsideration or appeal may be requested and during any period that any reconsideration or appeal is in process.
- 4000.5 The issuance of a CON, if required under the Act, shall be a condition precedent to the issuance of any license, permit, or any other type of official approval (except zoning approval) by any agency or officer or employee of the District government that is necessary for the project in addition to the CON.

- 4000.6 A CON shall be for a specific site, except that a proposed change of site within the same Advisory Neighborhood Commission shall not require further CON review if the change is made before the project is implemented. Any proposed change in the location of an approved service or facility outside the same Advisory Neighborhood Commission shall require application for a new CON.
- 4000.7 For the purpose of Subsection 4000.6, the term "official approval" shall mean final approval by the District government subject only to appeal.
- 4000.8 SHPDA shall not be required to issue a CON before an administrative budget review body approves a budget request that is under consideration by the Council because the project relies on the appropriation of funds from the District budget.
- 4000.9 For the purposes of Chapters 40 through 45 the term "major medical equipment" includes:
- (a) Equipment used for providing medical or health services acquired by lease, purchase, donation, or other comparable arrangement by or on behalf of a health care facility, or by or on behalf of any private group practice of diagnostic radiology or radiation therapy, for which the fair market value exceeds one million five hundred thousand dollars (\$1,500,000) adjusted from time to time to reflect changes in the Consumer Price Index; or
 - (b) A single piece of diagnostic or therapeutic equipment acquired by lease, purchase, donation, or other comparable arrangement by or on behalf of a physician or group of physicians, or an independent operator of the equipment, for which the fair market value exceeds two hundred and fifty thousand dollars (\$250,000) adjusted from time to time to reflect changes in the Consumer Price Index.
- 4000.10 For the purposes of Chapters 40 through 45 the term "major medical equipment" excludes medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services when it is independent of a physician's office or a hospital and satisfies the requirements of § 1861(s)(10) and (11) of the Social Security Act, approved August 14, 1935 (49 Stat. 420; 42 U.S.C. 1395x(s)).
- 4000.11 For the purposes of Chapters 40 through 45 an entity is "acquiring effective control" if it does any of the following:
- (a) Transferring, assigning, or otherwise disposing of fifty percent (50%) or more of the stock, voting rights thereunder, ownership interest, or operating assets of a corporation or other entity that is a health care facility (HCF) or is the operator or owner of an HCF;
 - (b) Engaging in a transaction that results in any person, or any group of

persons acting in concert, owning or controlling, directly or indirectly, fifty percent (50%) or more of the stock, voting rights thereunder, ownership interest, or operating assets of a corporation or other entity that is an HCF;

- (c) Engaging in a transaction that results in any person, or any group of persons acting in concert, having the ability to elect or cause the election of a majority of the board of directors of a corporation that is an HCF; or
- (d) Engaging in a conversion that results in the selling, transferring, leasing, exchanging, conveying, or otherwise disposing of, directly or indirectly, all the assets or a material amount of the assets, of a nonprofit HCF to a for-profit entity, whether a corporation, mutual benefit corporation, limited liability partnership, general partnership, joint venture, or sole proprietorship, including an entity that results from, or is created in connection with, the conversion.

4000.12 For the purposes of Chapters 40 through 45 a facility is considered a “diagnostic health care facility” if the facility is not operated by a hospital and is not the offices of a private physician or dentist, unless one (1) or more pieces of major medical equipment is located within the office, and is:

- (a) A diagnostic imaging center accredited by the American College of Radiology whose primary business is providing diagnostic imaging services to the public;
- (b) A cardiac catheterization laboratory;
- (c) A radiation therapy facility; or
- (d) An independent diagnostic laboratory whose primary business is providing diagnostic imaging services to the public at which at least three (3) of the following are performed:
 - (1) Magnetic resonance imaging;
 - (2) CAT scan;
 - (3) Nuclear medicine;
 - (4) Ultrasound;
 - (5) X-ray; or
 - (6) Mammography.

4001 STATE HEALTH PLANNING AND DEVELOPMENT AGENCY AND STATEWIDE HEALTH COORDINATING COUNCIL

4001.1 The project application and review files of SHPDA shall be open for public inspection and review during regular business hours.

4001.2 SHPDA shall duplicate CON documents for any person upon request and upon payment of the reasonable costs of duplicating the requested documents. SHPDA shall restrict access of the general public to portions of applications or supporting documents that contain detailed descriptions of security systems, medical record systems, controlled storage systems, or proprietary financial information.

4001.3 The Director shall provide information on the status of any review or on the status of any outstanding CON upon request.

4001.4 The Director may establish charges for all SHPDA studies, reports, data compilations, publications, or other types of documents. The charges shall be reasonably related to the costs of preparing, developing, retrieving, duplicating, and paying postage, where applicable.

4001.5 The review meetings of SHPDA and the Statewide Health Coordinating Council (SHCC) shall be open to the public.

4001.6 SHCC shall:

- (a) Assist SHPDA with developing the Health Systems Plan (HSP);
- (b) Review and make recommendations to SHPDA on the HSP; and
- (c) Make recommendations to SHPDA on CON applications.

4002 PRE-APPLICATION CONSULTATION WITH PROSPECTIVE APPLICANT

4002.1 A prospective applicant for a CON may consult with a designated member of SHPDA staff before submitting a Letter of Intent for any project and during the application process.

4002.2 The Director shall assign a staff person to assist each applicant for a CON. The applicant shall consult with the assigned SHPDA staff person throughout the application process, except during any period for which *ex parte* contacts are prohibited under Section 4305 and D.C. Official Code § 44-409(i).

4002.3 SHPDA staff shall:

- (a) Review with the applicant the procedures and criteria that SHPDA will follow during the application review;

- (b) Provide technical assistance on information required in the application;
- (c) Provide a tentative schedule for review of the application; and
- (d) Provide other assistance that may be helpful to the applicant.

4002.4 Consulting with SHPDA staff before applying for a CON shall not relieve an applicant from the requirement to file a formal Letter of Intent pursuant to Section 4003. Pre-application consultation shall not commit SHPDA to issuing a CON and shall not represent SHPDA's official position concerning an application submitted subsequent to the consultation.

4003 LETTER OF INTENT AND PUBLIC NOTICE

4003.1 Before submitting a formal application for a CON, an applicant shall submit a Letter of Intent to the Director for the purposes of notifying SHPDA that an application for a CON will be forthcoming and providing SHPDA sufficient time to prepare for application review. The Letter of Intent shall contain the following information:

- (a) The name, address, and telephone number of the applicant;
- (b) The name of an individual authorized to respond to SHPDA staff questions regarding the application;
- (c) The proposed location for the health care facility, health service, or other entity; and
- (d) A brief description of the proposed health care facility, health service, or other entity, including its cost and the projected date of implementation.

4003.2 The applicant's chief executive officer or a person authorized to act on behalf of the chief executive officer shall sign the Letter of Intent.

4003.3 An applicant shall provide notice to the community of its intent to file a CON application by publishing a notice in a newspaper of general distribution within the District of Columbia that generally describes the proposed project and states that the Letter of Intent will be filed with SHPDA.

4003.4 An applicant shall submit the Letter of Intent to SHPDA at least sixty (60) days but not more than one hundred eighty (180) days before filing the application for a CON and shall include with the Letter of Intent a copy of the notice required by Section 4003.3.

4003.5 An applicant may submit an application after consulting with SHPDA staff.

- 4003.6 The Director shall designate a SHPDA staff member to assist the applicant upon filing of a Letter of Intent.
- 4003.7 If an applicant has not submitted a CON application within one hundred eighty (180) days after submitting the Letter of Intent, the Letter of Intent shall be void unless the applicant requests and receives written approval for an extension to file the CON application.
- 4003.8 An applicant may request one (1) extension of not more than one hundred eighty (180) days. The request shall be made in writing before the initial one hundred eighty (180) day period expires. The Director shall respond to the request in writing and may grant an extension of one hundred eighty (180) days or less.
- 4003.9 SHPDA may use the period of time after receiving a Letter of Intent and before receiving a formal application for a CON to do the following:
- (a) Answer inquiries concerning the requirements for a CON;
 - (b) Advise the applicant on appropriate joint planning with other HCFs, HMOs, and affected parties; and
 - (c) Advise the applicant on the involvement of other community and public agencies, providers, and consumers in the long and short-range planning of the applicant.
- 4003.10 SHPDA shall provide technical assistance to individuals and public and private entities for obtaining and completing the form necessary for preparing an application.

4004 CONDITIONAL CERTIFICATES OF NEED

- 4004.1 SHPDA may require an applicant to comply with certain conditions when granting a CON, provided that the conditions relate directly to an adopted SHPDA review criteria.
- 4004.2 The expiration date, if any, of each condition shall be specified in the CON.
- 4004.3 If a CON holder violates a condition of a CON, the Director shall issue the CON holder written notice of the violation and may revoke the CON using the procedure for noncompliance with the CON, as specified in Section 4010.
- 4004.4 If the Director determines that the applicant has violated a condition and is not permitted to begin full operation, the applicant may appeal in the same manner as with any decision to issue or not issue a CON.
- 4004.5 The completed application for a CON and related documentation shall be

considered to be a part of any CON issued after review and approval of the application.

4004.6 The CON holder shall proceed only in compliance with the CON and the related application and documentation that the Director has approved.

4004.7 In the case of an application approved for a CON with conditions, SHPDA may (if no licensing or operating approval is required by any other District agency) grant the CON holder the authority to begin "conditional operation" while the CON holder demonstrates its compliance with the conditions attached to the CON.

4005 PROPOSED CHANGES IN APPROVED PROJECTS

4005.1 The Director shall specify in the CON the maximum amount of capital expenditure that may be obligated under the CON.

4005.2 A CON holder shall report a proposed change in the project budget that will result in an expenditure greater than the maximum capital expenditure specified in the CON.

4005.3 A CON holder shall request the Director's approval for a proposed change in the project budget that will result in an expenditure that is twenty-five per cent (25%) or more larger than the approved capital expenditure specified in the CON. The Director shall issue a decision on a proposed change in not more than thirty (30) days after receiving a request to modify the project budget. A CON holder shall not commence work on the proposed changes that are twenty-five per cent (25%) or more than the maximum capital expenditure before the Director approves the modification.

4005.4 A CON holder shall report cumulative costs of individual budget changes to the Director for review and approval as part of the CON holder's regular, periodic reports. A CON holder shall submit a new application for any proposed change that exceeds the proposed budget by more than fifty per cent (50%) of the approved capital expenditure.

4005.5 Except for routine construction change orders, the purpose of which is to correct architectural or engineering errors or to compensate for errors in "as built" drawings of existing buildings, errors in surveys, or similar types of errors, all proposed changes to an approved project budget shall be promptly reported to SHPDA.

4005.6 A CON holder shall report routine construction change orders when the CON holder reports completion of the project.

4005.7 If the Director determines that a proposed non-budgetary change will not affect patient care, the Director may approve the change (subject to reconsideration and

appeal) without referring the change to SHCC for review. If the Director approves a change pursuant to this subsection, the Director shall notify SHCC of the change at the next monthly meeting of SHCC.

- 4005.8 If patient care is not significantly affected, and, if either of the following conditions is met, SHPDA shall approve or disapprove the change without referral to SHCC, and shall notify SHCC at the next scheduled SHCC meeting:
- (a) The cost increase is directly related to inflation, unforeseen construction difficulties, or changes in building plans in the nature of routine change orders consistent with the CON application approved by SHPDA; or
 - (b) The cost increase involves changes in acquisition plans from lease or similar arrangements to purchase or vice versa (if the change is economically justifiable as determined by SHPDA).
- 4005.9 If a new CON is required pursuant to Subsection 4005.4, the Director shall consider the date of issuance of the original CON to be the date of issuance of the consolidated CON for all SHPDA purposes, including quarterly reports and extension schedules.
- 4005.10 A CON holder shall report each proposed change to the specifications (as stated in the approved CON) of a project. This report shall include any service, any equipment, and any other type of change whatsoever to the specifications of an approved project.
- 4005.11 If the Director determines that a proposed non-budgetary change will not significantly affect patient care, the Director may issue a decision that the change may be made (subject to reconsideration and appeal) without prior approval of the SHCC.
- 4005.12 SHPDA shall update its files concerning the nature of the change and shall notify the SHCC at the next scheduled SHCC meeting.
- 4005.13 If the Director finds that a proposed non-budgetary change would substantially affect patient care, the Director shall require the CON holder to apply for and receive a new CON before the proposed change may be implemented.
- 4005.14 If a new CON is required under Subsection 4005.13, SHPDA shall consider the date of issuance of the original CON to be the date of issuance of the consolidated CON for all SHPDA purposes, including quarterly reports and extension schedules.
- 4005.15 A proposed change in a completed project associated with a capital expenditure for which SHPDA has previously issued a CON shall require review and issuance of a new CON if the change is proposed within two (2) years after the date the

activity for which the expenditure was approved is undertaken. (For example, if a hospital receives approval to construct a new wing, the hospital will “undertake the activity” when it begins to provide services in the wing. If, in the two (2) years after undertaking the activity, the hospital decides to increase the number of beds in the wing by a number that would not otherwise trigger a review, a review would still be required.). For the purposes of this section, a CON holder has undertaken an activity when it begins to provide services under the CON.

4005.16 The provisions of Subsection 4005.15 shall apply to a change associated with capital expenditures that are subject to review under this title.

4005.17 SHPDA review and approval shall be required regardless of whether a capital expenditure is associated with the proposed change.

4005.18 A “change in a project” shall include, at a minimum, any change in the bed capacity of a facility or the addition or termination of a health service.

4006 PRE-OPERATIONAL INSPECTION

4006.1 A CON holder shall not begin operation of an approved project until SHPDA has conducted a preoperational inspection and has determined that the project is in compliance with the CON requirements.

4006.2 For a large project that may be completed in phases, the Director may approve the project in phases as the phases are completed and after a CON holder requests phased implementation of the project in writing.

4006.3 Not later than thirty (30) days before the date that the CON holder proposes beginning operation, the CON holder shall inform the Director in writing of the proposed date for operation of the facility or service (or a part of the facility) approved under a CON.

4006.4 After the notification required by Subsection 4006.3, SHPDA shall conduct an on-site pre-operational inspection and review for compliance with all CON requirements.

4006.5 The CON Holder shall make all portions of the facility or service available for inspection and shall produce all records, including cost records, SHPDA deems necessary to determine compliance with the specifications of the approved CON.

4006.6 The CON holder shall not begin operation without a Letter of Completion. If, after inspection, the Director determines that a project, or an operational portion of a project, is substantially complete, and that the CON holder has satisfied all requirements and specifications of the CON, the Director shall issue a Letter of Completion for that project or an operational portion of the project.

- 4006.7 If all phases of a project are completed, receipt of the Letter of Completion issued under Subsection 4006.6 terminates the CON review process, provided that all conditions included in the CON that have continuing applicability shall remain in effect.
- 4006.8 If the Director determines that a project, or an operational portion of a project, is not substantially complete or is not in compliance with all requirements of the CON, the Director shall notify the CON holder in writing of the deficiencies.
- 4006.9 A notice of deficiency issued pursuant to Subsection 4006.8 shall:
- (a) Identify the parts of the project that are not complete;
 - (b) Identify any deficiencies regarding the requirements for the project; and
 - (c) Identify the steps necessary for the CON holder to complete the project or correct deficiencies.
- 4006.10 A CON holder may request reconsideration of, and appeal, a notice of deficiency as if the notice was a denial of a CON, pursuant to Chapter 43 of this title.

4007 ISSUANCE AND EXTENSION OF CERTIFICATE OF NEED

- 4007.1 A CON shall be issued for a period of up to three (3) years as the Director determines to be appropriate. An applicant may request, and the Director may grant, an applicant's written request for a CON period of less than three (3) years.
- 4007.2 The Director may grant an extension of an expiring CON for a period of up to four (4) years, including the original term and excluding any administrative extensions that may have been granted, upon a written showing of substantial progress or a justification for lack of progress.
- 4007.3 For purposes of this section, the phrase "substantial progress" means reasonable compliance with SHPDA-approved schedule for the project.
- 4007.4 For purposes of this section, the phrase "justification for lack of progress" means an explanation acceptable to the Director for the CON holder's non-compliance with the SHPDA-approved schedule, and may include factors beyond the control of the CON holder.
- 4007.5 SHPDA shall extend or deny an extension of a CON based on the quarterly progress reports filed by the CON holder under Section 4008 and any additional information required by this chapter.
- 4007.6 The "SHPDA-approved schedule" shall be the latest of the following:

- (a) The final schedule submitted for approval in the applicant's CON application;
- (b) The schedule required by SHPDA in any condition of a CON; or
- (c) The schedule approved by SHPDA in an extension.

4007.7 If the applicant has not made substantial progress, SHPDA shall issue a ninety (90) day administrative extension of the CON for the purpose of allowing SHPDA to commence proceedings for revoking the CON under the provisions of Section 4010.

4007.8 If an applicant has made substantial progress but there has been a deviation from another aspect of the approved application, and the Director intends to grant an extension, SHPDA may require the applicant to comply with the previously approved requirements or a SHPDA-approved modification of those requirements.

4007.9 The Director's decision to extend or not extend a CON may be appealed under the provisions of Chapter 43 of this title.

4007.10 The Director may grant an administrative extension of the validity of a CON for up to ninety (90) days for good cause, which may include a showing that the project is within ninety (90) days of completion.

4007.11 A CON that is not extended shall be void.

4007.12 A CON holder requesting extension of a CON beyond a total of four (4) years shall submit a new application for a CON for the project to SHPDA no later than six (6) months before the current CON expires.

4007.13 If a CON holder provides written assurance that the project will be completed within six (6) months after the expiration of its current CON, including any extension up to but not exceeding a total of four (4) years, SHPDA may grant an additional administrative extension for up to six (6) months without the need for an applicant to submit a new CON application.

4008 PROGRESS REPORTS

4008.1 A CON holder shall make quarterly progress reports to SHPDA.

4008.2 A progress report shall include the following information, if applicable:

- (a) Original CON registration number;
- (b) Status of the project, including current estimated completion date, in

relation to the SHPDA-approved construction schedule, and any revised construction schedule reported in previous quarterly progress reports but not yet approved by SHPDA;

- (c) Reasons for not progressing at the rate contemplated in the most recently approved schedule, if applicable;
- (d) Any events that might delay or halt future progress, and actions to be taken in response to these events, if applicable;
- (e) Any changes in the proposed schedule and justification for those changes;
- (f) Changes in the scope of the project or program approved in the CON (if there are changes, submit copies of revised construction drawings, specifications, leases, or other relevant documentation);
- (g) An itemization of any changes in the project's cost from those approved by SHPDA, and as modified in previous quarterly progress reports;
- (h) A statement of the current means of financing the project, and the continued adequacy of the financing;
- (i) Any foreseeable events that might jeopardize financing, and the proposed response to an event that could jeopardize financing;
- (j) A description of efforts made toward complying with any conditions of the CON; and
- (k) Other pertinent supplemental information the CON holder wishes to bring to the Director's attention or other information the Director specifically requests that relates to the project.

4008.3 The Director may request additional information after receiving a progress report if the Director determines that the report is not complete.

4008.4 The Director may approve or deny a request for a CON extension without submitting the extension request to the SHCC, unless the request would require submission of a new application and full review.

4008.5 SHPDA staff shall prepare a memorandum of the progress made by the CON holder receiving the complete progress report for the third (3rd) quarter of each CON year. The analysis shall include the following:

- (a) The project's rate of progress according to the most recent SHPDA-approved schedule for the project;

- (b) Whether any reported delay is beyond the control of the CON holder;
- (c) Whether the CON holder will complete the project on schedule;
- (d) Whether any change in the proposed schedule is reasonable with respect to the health requirements of District residents and visitors;
- (e) Whether any cost changes exceed the rate of inflation for construction projects in the District;
- (f) Whether the CON holder has minimized costs;
- (g) Whether financing for the project continues to be adequate;
- (h) Whether the CON holder is continuing to comply with any conditions of the CON; and
- (i) Whether the project continues to be adequate with respect to all review criteria, except those for need and conformance to the State Health Plan.

4008.6 SHPDA staff shall make a recommendation to the Director about whether to issue an extension for a CON under Section 4007 or to take action under Section 4010 to revoke a CON.

4009 SALE OR TRANSFER OF EFFECTIVE CONTROL

4009.1 Pursuant to D.C. Official Code § 44-411 a CON may not be sold or transferred. The sale or transfer of effective control over a project for which a current CON has been granted shall cause the CON to be subject to review and approval by SHPDA. The process for reviewing a CON resulting from transfer of effective control is subject to the requirements of D.C. Official Code § 44-406(b) and this section. For the purpose of this section, a current CON means authorization from SHPDA that has not been fully implemented.

4009.2 For purposes of this section the term “effective control” includes:

- (a) The ability of any person, by reason of a direct or indirect ownership interest, whether of record or beneficial, in a corporation, partnership, or other entity that holds a CON, to direct or cause the direction of the management or policies of that corporation, partnership, or other entity; and
- (b) Creation of a new legal entity regardless of whether the owners remain the same.

4009.3 If a current CON is held by a partnership, either general or limited, the addition of a general partner who was not identified as a general partner in the certificate of

partnership on file with SHPDA at the time the original CON was issued, or the succession of a general partner who was named as a general partner by another person at any time after issuance of the original CON, shall be reviewed and approved by SHPDA, or shall cause withdrawal of the CON, effective as of the time at which the addition or succession of a general partner occurs.

- 4009.4 Any transfer, assignment, or other disposition of ten per cent (10%) of the stock or voting rights thereunder of a corporation or other entity that operates a health care facility, or any transfer, assignment, or other disposition of the stock or voting rights thereunder of the corporation or other entity that results in the ownership or control of more than ten percent (10%) of the stock or voting rights of the corporation or other entity by any person shall, when that corporation or entity holds a current CON, shall cause the CON to be subject to review and approval by SHPDA.
- 4009.5 For a partnership, ten percent (10%) of the stock or voting rights shall include the following:
- (a) The obligation of any partner to provide ten percent (10%) or more, including property and services, of the total capital contribution of the partnership, as reflected in an amendment of the original certificate of partnership;
 - (b) The right of any partner to receive distribution of ten percent (10%) or more of the profits of the partnership, as reflected in an amendment of the original certificate of partnership; or
 - (c) The right of any partner, upon dissolution of the partnership, to receive ten percent (10%) or more of partnership assets remaining after payment of all partnership debts, as reflected in an amendment of the original certificate of partnership.
- 4009.6 A party proposing to gain effective control of a project for which a CON has been granted, or of an entity that holds a CON, shall apply for a new CON. No Letter of Intent shall be required in this circumstance.
- 4009.7 The criteria and standards normally applicable to a CON application shall apply to a sale or transfer of effective control. SHPDA shall also weigh the qualifications of the party proposing to gain effective control to effectively operate the project.
- 4009.8 SHPDA shall review a CON application under this section by examining the financial responsibility and business interests of the person or entity seeking to obtain the effective control in addition to any other prescribed and published SHPDA review criteria.
- 4009.9 Under D.C. Official Code § 44-416(e), failure to obtain a new CON before

effecting the sale, transfer, assignment, or other disposition of effective control over, or the acquisition of ten per cent (10%) or more of stock or voting rights, in the holder of record of a current CON shall cause the automatic revocation of the current CON, effective as of the time at which the acquisition, sale, transfer, assignment, or other disposition occurs.

4010 ENFORCEMENT AND REMEDIES FOR NONCOMPLIANCE

- 4010.1 The Director may request that the Office of the Attorney General enjoin the activities of a person offering, developing, or operating a health care facility in violation of the Act, as specified in D.C. Official Code § 44-416(b).
- 4010.2 The Director may revoke a current CON, after holding a hearing to ascertain the facts. If the Director finds that a person has violated a provision of the Act or 22 DCMR Chapters 40 through 45, the Director may take action to revoke a current CON even though action has been initiated to criminally prosecute, sue for injunctive relief, or impose a civil fine, penalty, or fee for a violation of the Act or Title 22 Chapters 40 through 45.
- 4010.3 The Director may revoke a current CON for lack of substantial progress under this chapter.
- 4010.4 Before revoking a CON, the Director shall publish a notice of alleged violation or lack of substantial progress in a newspaper of general circulation in the District, and shall notify all interested parties, including the CON holder.
- 4010.5 The notice shall include a detailed description of the alleged violation or lack of substantial progress and shall provide the time and location of a public hearing to consider the alleged violation.
- 4010.6 The public hearing shall be held no sooner than fourteen (14) days from the date of the notice and no later than thirty (30) days from that date.
- 4010.7 The hearing shall be conducted according to the procedures specified in chapter 43 of this title for reconsideration hearings, except that the SHPDA staff person in charge of a CON review, or a designee, shall have up to one (1) hour to present the details of the alleged violation or lack of substantial progress. Following this presentation, the CON holder may question the SHPDA staff person.
- 4010.8 The CON holder shall have up to one (1) hour to make its presentation, after which SHPDA staff may ask questions of the CON holder. Other persons may then testify.
- 4010.9 Following all testimony, the CON holder may make a ten (10) minute closing statement.

4010.10 The Director shall decide whether to revoke a CON within thirty (30) days following the close of the public hearing. The Director's decision shall be:

- (a) Written;
- (b) Based on the complete record of the withdrawal action; and
- (c) Include findings of fact and conclusions of law.

4010.11 There shall be no *ex parte* contacts between the CON holder and SHPDA staff or the SHCC following the public hearing and before the Director issues a decision.

4010.12 The Director's decision to revoke a CON may be appealed to the Office of Administrative Hearings without further reconsideration by the Director.

4011 NOTICE OF CERTAIN CAPITAL EXPENDITURES

4011.1 A health care facility or service (except an HMO exempt under D.C. Official Code § 44-407(c) and 22 DCMR 4109) shall notify SHPDA that it intends to obligate an expenditure of two million five hundred thousand dollars (\$ 2,500,000) or more for construction, repairs, or renovation of facilities, when that action requires issuance of any type of permit from the District government notwithstanding that the capital expenditure intended is less than the CON review threshold.

4011.2 A health care facility or service shall submit with the notice either of the following:

- (a) A summary of the project, including total estimated capital expenditure; or
- (b) A copy of the required permit application filed with the appropriate District government agency or agencies.

4011.3 The notice shall contain a description of any related capital construction repairs or renovations that the facility may consider undertaking within two (2) years of the completion of the work for which notification is presently being given.

4011.4 The health care facility or service shall file notice with SHPDA at least ninety (90) days before undertaking the construction, repairs, or renovation in question.

4011.5 A health care facility or service, except an HMO exempt under Chapter 41, shall notify SHPDA of its intention to obligate an expenditure to acquire by lease, donation, or other transfer, any major equipment. Notice shall be given not less than thirty (30) days before acquiring the equipment.

4011.6 A health care facility or service, except an HMO exempt under Chapter 41, shall

notify SHPDA of its intention to acquire by lease, donation, or other transfer, diagnostic or medical treatment equipment (including the replacement of parts of existing equipment that enhance the original capabilities of the equipment), whether a single unit or system with related functions, the fair market value of which is under one million five hundred thousand dollars (\$1,500,000). Notice shall be given not less than thirty (30) days before acquiring the equipment.

- 4011.7 The notice required by Subsections 4011.5 and 4011.6 shall include:
- (a) The purchase price or fair market value of each item of equipment to be obtained;
 - (b) Each item's function;
 - (c) The services and locations within the facility that will be affected by the equipment acquisition; and
 - (d) A description of functionally related equipment extensions or enhancements that the facility may consider purchasing within two (2) years of putting the equipment described in the notice into operation.
- 4011.8 If the Director determines that the activity described in the notice is related to subsequent action to be taken within the two (2) year period and should be considered a single project, a CON review shall be required when the total cost of the present and subsequent actions exceeds the capital expenditure threshold for CON review.
- 4011.9 If a health care facility or service, except an HMO exempt under Chapter 41, intends to undertake related construction, repairs, or renovations, or intends to acquire functionally related equipment, extensions or enhancements to equipment not describe in a notice to SHPDA, the additional activities or equipment shall be subject to CON review when the total cost within a given two (2) year period exceeds the capital expenditure threshold for CON review.
- 4011.10 SHPDA shall conduct an expedited review of a CON application required under this section, and the applicant shall not be required to file a letter of intent.
- 4011.11 The Director's determination under this section that intended action by a health care facility or service is subject to CON review may be appealed by an affected person to the District of Columbia Office of Administrative Hearings.
- 4012 GENERAL CRITERIA AND STANDARDS FOR REVIEW**
- 4012.1 Whenever a criterion or standard requires proof of a fact, the applicant shall have the burden of affirmatively proving that fact.
- 4012.2 The criteria and standards set forth in this section shall apply to every CON

application other than an application that relates to acquiring an existing health care facility.

4012.3 Each project shall conform to the general provisions, defined priorities, goals, objectives, recommended actions, criteria, and standards contained in the State Health Systems Plan (HSP) and the Annual Implementation Plan (AIP) for the development of health facilities or services, if applicable.

4012.4 Each project shall be consistent with the applicant's long range development plan.

4012.5 Each project shall be consistent with non-health sector plans for the service area of the proposed facility or service. The applicant shall demonstrate consistency by providing evidence and assurances that:

- (a) It has considered other plans adopted or endorsed by the District, including public and private transportation, housing, and economic development that will impact the area the facility or service serves; and
- (b) The proposal is consistent with those plans specified in subsection (a).

4012.6 Each applicant shall demonstrate the need for the project on a health care system wide basis (for those projects that substantially affect patient care). The applicant shall demonstrate need by meeting the following standards:

- (a) The applicant shall provide evidence and assurances that the project is needed to meet service or facility levels required for the District as specified in the HSP. If a proposal serves a geographic area larger than the District, the applicant shall document that the project is needed to meet the service or facilities requirements of the larger area as specified in the HSP.
- (b) If the HSP does not specify need, the applicant shall provide evidence and assurances that the project is needed based on a special analysis of the District or larger area service and facility needs. This study shall consider the utilization rates of the same or similar services of the applicant and other providers.
- (c) If the application involves new technology, the applicant shall provide evidence and assurances of the developmental level of the technology and the extent to which it has been proven to be beneficial in controlled trials comparing its use with the use of conventional techniques or equipment. Applications involving new technology that has not been proven to the satisfaction of the Director to be beneficial in controlled trials shall not be considered needed unless the applicant proposes to conduct the trials in addition to providing patient care.

- (d) An application involving new technology that has been proven to the satisfaction of the Director to be generally accepted by the scientific community as beneficial in controlled trials shall also demonstrate that other actual or potential applicants that might more appropriately be given approval for acquisition of the new technology:
 - (1) Already have the technology or have SHPDA approval for its acquisition and that an additional need for the technology to meet patient requirements exists; or
 - (2) Will not seek approval to acquire the new technology within (12) months of the application date. The applicant shall identify other actual or potential applicants considering the following:
 - (A) The number of beds operated;
 - (B) Teaching programs;
 - (C) Research programs;
 - (D) Current or approved specialized units or specialized services provided; and
 - (E) Current or approved special capabilities in terms of equipment and personnel skills.
- (e) The Director shall consider the special needs and circumstances of an applicant, as documented by the applicant, for an application from an entity that provides a substantial portion of its services or resources, or both, to individuals from outside the metropolitan area.

4012.7 Each applicant shall demonstrate need for the project on an institutional basis by providing evidence and assurances that the project is required to meet institutional needs.

4012.8 Each applicant shall satisfy the criterion of availability of training opportunities by meeting the following standards:

- (a) An applicant shall provide evidence and assurances that the proposed project will not negatively impact opportunities for health professional training if a health profession school or program asserts, and the Director agrees, that training opportunities are necessary; and
- (b) If the Director finds that a project is not otherwise needed under the criteria in Subsections 4012.5 and 4012.6, an applicant may provide evidence that the project is needed to provide reasonable access to training

opportunities in operating services.

4012.9 Each applicant shall satisfy the criterion for requirements of research projects and programs by meeting the following standards:

- (a) An applicant shall provide evidence and assurances that the proposed project will not negatively impact the availability of facilities and equipment needed for biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages, as determined by the Director; and
- (b) If the Director finds that a project is not otherwise needed, an applicant may provide evidence that a project is essential to meeting the reasonable needs of biomedical or behavioral research projects that are designed to meet a national need and for which local conditions offer special advantages, as determined by the Director.

4012.10 Each applicant shall satisfy the criterion for the schedule for project implementation by providing evidence and assurances that the proposal, if approved, will be implemented in a prompt and orderly fashion consistent with the approved schedule and public need for the service or facility and cost containment in project implementation.

4012.11 Each applicant shall satisfy the criterion for the effect of operating policies, personnel capabilities, and the physical structure on the proposed project's care of patients, patient accessibility to medical care, and patient understanding of medical care by meeting the following standards:

- (a) An applicant shall provide evidence and assurances that the project will not negatively impact services available to the following:
 - (1) Service area ethnic populations who speak a language other than English;
 - (2) Low-income residents;
 - (3) Persons with physical or mental disabilities;
 - (4) Racial and ethnic minorities;
 - (5) Women;
 - (6) Elderly persons;
 - (7) Persons whose care is paid for by Medicaid, Medicare, public medical assistance programs, or other public programs;

(8) Persons uninsured or who have limited insurance coverage; and

(9) Other under-served groups.

(b) An applicant shall provide evidence and assurances that access to care is not unreasonably restricted by its admissions policies, requirements, or hours of operation. If an application is for major medical equipment, unless otherwise specified in the HSP for specific types of equipment, not otherwise exempt, the standard for this criterion shall not be considered met unless the equipment is regularly scheduled for operation at least fifty (50) hours per week, fifty-two (52) weeks per year and is available for emergency use at all other times, if the equipment is of a type reasonably expected to be necessary for emergency care.

4012.12 Each applicant shall satisfy the criterion for compliance with uncompensated care and community service requirements. The standard for satisfying this criterion is by providing evidence and assurances of compliance with applicable provisions of § 11 of the Act (D.C. Official Code § 44-410) as well as the following:

(a) An applicant that has not previously held a CON shall provide assurances of prospective compliance; and

(b) An applicant that has previously held a CON shall provide evidence of past compliance and assurances of prospective compliance.

4012.13 Each applicant shall satisfy the criterion for involvement of the community in the process of project planning and development. The standard for satisfying this criterion is by providing evidence and assurances of opportunities for community participation in the preparation and development of the project through the following:

(a) Public notice of the project to affected Advisory Neighborhood Commissions (ANC's); and

(b) Consideration of comments received from community agencies, groups, and individuals.

4012.14 Each applicant shall satisfy the criterion for impact of the proposed project on the health system and the health of District residents and visitors. The standard for satisfying this criterion is by providing evidence and assurances that the project, if it involves a direct patient care service, will not adversely impact the health care system and the health of the public in terms of health status as measured by industry standards, such as hospital admissions, emergency room visits, length of stay, and other relevant measures.

- 4012.15 Each applicant shall satisfy the criterion for observance of rights of patients. The standard for satisfying this criterion is by providing evidence and assurances of the applicant's mechanism for guaranteeing patient's rights. Minimal compliance with this standard requires compliance with all federal and District laws and regulations regarding patient rights.
- 4012.16 Each applicant shall satisfy the criterion for assurance that the care to be provided is of acceptable quality. The standard for satisfying this criterion is by providing evidence and assurances that it will meet professional and community standards of quality care. The applicant shall document compliance with this standard by showing that the project conforms to the requirements of District and federal regulatory agencies and recognized accreditation bodies including the Joint Commission on the Accreditation of Health Care Organizations and the Commission on Accreditation of Rehabilitation Facilities.
- 4012.17 Each applicant shall satisfy the criterion for compliance with building and equipment requirements. The standard for satisfying this criterion is by providing evidence and assurances that all new construction meets the standards contained in minimum requirements of latest edition of *Guidelines for Design and Construction of Health Care Facilities*, and District construction and licensing codes and regulations, as applicable to the type of project proposed. A remodeling project shall satisfy as many of these requirements as are reasonably practical, as determined by the Director, acting in consultation with District licensing and construction authorities.
- 4012.18 Each applicant shall satisfy the criterion for selection of the best of alternative means of providing the project's services. The standard for satisfying this criterion is by providing a description of the alternatives the applicant considered, and the findings that led the applicant to select the proposed approach rather than an alternative approach. The applicant shall select the most favorable alternative available by evaluating and comparing the final selected plan with the following alternative means:
- (a) If shared services are not proposed, the applicant shall demonstrate why shared services are not practical or cost effective;
 - (b) If a merger is not proposed, the applicant shall demonstrate why a merger agreement is not desirable or practical;
 - (c) The applicant shall demonstrate that the proposed method for providing services, whether provided in-house or contracted out, is more desirable than the alternative. Where applicable, the estimated costs for both contract and in-house services should be presented;
 - (d) The applicant shall demonstrate that the option of taking no action is not desirable; or

- (e) The applicant shall demonstrate that it considered other alternatives and demonstrate why they were considered less desirable.

4012.19 Each applicant shall satisfy the criterion for the effect of operational costs of the project on general costs, rates, or consumer charges. The standard for satisfying this criterion is by providing evidence and assurances that the project will reduce costs or charges for the service in question and for related services to the maximum practical extent or increase cost and charges to the minimum practical extent, consistent with benefits provided, if any. Unless a different standard is adopted in the HSP for a specific service, projects that are projected to operate at less than eighty percent (80%) utilization of available capacity in their third (3rd) year of operation, given operating hours determined by the Director to be reasonable, shall be deemed not to meet this standard. The Director may consider special circumstances concerning utilization for teaching and research in determining compliance with the utilization rate standard.

4012.20 Each applicant shall satisfy the criterion for the effect of operational costs of the project on the applicant's budget. The standard for satisfying this criterion is by providing evidence and assurances that the applicant's operating cost and revenue analysis show that the project will not substantially negatively affect the applicant's continuing financial operational viability, given reasonable revenue and volume projections.

4012.21 Each applicant shall satisfy the criterion for adoption of energy conservation techniques. The standards for satisfying this criterion are as follows:

- (a) If a project is designed to conserve energy, the applicant shall provide evidence and assurances that the proposal is the most cost effective and practical means available and that over the life cycle of the facility the proposal will result in reduced costs; and
- (b) If a project is not designed primarily to conserve energy, if construction or equipment replacement is involved in the project, the applicant shall provide evidence and assurances that the project incorporates the most cost effective and practical energy conservation techniques over the life cycle of the project.

4012.22 Each applicant shall satisfy the criterion for effect on competition. The standards for satisfying this criterion are as follows:

- (a) If a new service does not involve capital expenditures of an amount that would otherwise require a CON review, the applicant shall provide evidence and assurances that the project will positively affect competitive factors and result in a more appropriate supply of services at lower charges or at charges no higher than is justified by the benefits of its more

appropriate availability, quality, and other features; and

- (b) For all other projects, including acquisitions, the applicant shall provide evidence and assurances that the project will not adversely affect competition or an adequate supply of services.

4012.23 Each applicant shall satisfy the criterion for efficiency and effectiveness of existing services. The standards for satisfying this criterion are as follows:

- (a) If an application proposes to modernize a service, to replace equipment, or to expand a service, an applicant shall provide evidence and assurances that the results of the proposed modernization, service expansion, or equipment replacement cannot be achieved by reasonable increases in the applicant's efficiency or effectiveness, including reasonable changes in operating hours, more efficient use of other equipment, use of revised procedures, better scheduling of services, or referral to other providers; and
- (b) For a proposed new service, an applicant shall provide evidence and assurances that the proposal is the most efficient, effective, and practical manner of providing needed services, considering not only alternatives that the applicant might offer but also the operations or potential operations of other providers.

4012.24 Each applicant shall satisfy the criterion for construction plan design and specification alternatives. The standard for satisfying this criterion is by providing evidence and assurances that the construction methods and material specifications selected are the most cost effective over the life cycle of the proposed project, taking construction, energy, operating, and maintenance costs into consideration.

4012.25 Each applicant shall satisfy the criterion for financial viability of project operation. The standard for satisfying this criterion is by providing evidence and assurances that sufficient financial resources are available, not only to complete the project but also to sustain operations for at least two (2) years. Financial resources that may be used to meet this requirement include:

- (a) Reserves for start-up costs; and
- (b) Patient revenue, based on estimated patient volume, payer mix, and reimbursements the Director determines to be reasonable. Reimbursements and projected patient volume are not reasonable if the projections are based, in whole or in part, providing services that are inconsistent with the criterion and standard specified in Subsection 4012.27.

- 4012.26 Each applicant shall satisfy the criterion for availability of required capital. The standard for satisfying this criterion is by providing evidence and assurances that the proposed source of funds, including loans, are fully described, to the extent possible at the time of proposal submission for the project review. Each proposed loan agreement shall be accompanied by information on duration and repayment terms. The applicant shall provide evidence and assurances that more favorable financial arrangements cannot be obtained. The financial arrangements shall be reasonable when compared to those for other similar projects.
- 4012.27 Each applicant shall satisfy the criterion for compatibility with the reimbursement policies of third-party payers, where applicable. The standard for satisfying this criterion is by providing evidence and assurances that the applicants proposed services are reimbursable by third-party payers (including Medicare and Medicaid) if the third-party payers reimburse other providers in the District for providing the same services.
- 4012.28 Each applicant shall satisfy the criterion for availability of personnel. The standard for satisfying this criterion is by providing evidence and assurances that the proposal includes adequate qualified personnel and that the required personnel can be obtained without substantial negative effects on other services the applicant or other providers offer.
- 4012.29 Each applicant shall satisfy the criterion for management capability. The standard for satisfying this criterion is by providing evidence and assurances of a stable and competent background in the administration and conduct of existing programs, if any, and demonstrating the ability to conduct the proposed program in a competent and effective manner.
- 4012.30 Each applicant shall satisfy the criterion for availability of ancillary services, as required. The standard for satisfying this criterion is by providing evidence and assurances that required ancillary or support services necessary for operation of a proposed facility or service shall be available within the applicant's existing operation, through supply agreement with another provider, or as a part of the proposal.
- 4012.31 Each applicant shall satisfy the criterion for relationship of the project to the health care system. The standard for satisfying this criterion is by providing evidence and assurances that clearly define the relationship of the proposed project to existing services and facilities in the health care system, and the effect of the project on other facilities and services, including those of other providers. The applicant shall demonstrate appropriate linkages to ensure continuity of care.
- 4012.32 The general criteria set forth in Subsections 4012.33 and 4012.34 shall be applicable to applications submitted by HMOs.
- 4012.33 Each HMO applicant shall satisfy the criterion for need for the project to meet the

needs of enrolled members of the HMO (or combination of HMOs) and to meet the needs of reasonably anticipated new members. The standard for satisfying this criterion is by providing evidence and assurances that the proposed project is reasonably required to meet the health care needs of the HMO members or future members who can be expected to use the proposed service or facility.

4012.34 Each HMO applicant shall satisfy the criterion for reasonable availability of the proposed service or facility only through direct provision by the applicant HMO. A proposed service or facility is presumed not to be reasonably available to an HMO other than by direct provision by the HMO (or group of HMOs) unless the Director determines that the proposed facility or service:

- (a) Would be available to the HMO under a contract, lease, or similar arrangement of at least five (5) years duration;
- (b) Would be reasonably available and conveniently accessible through physicians and other health professionals associated with the HMO (for example, HMO physicians having full staff privileges at a non-HMO hospital);
- (c) Would not cost appreciably more than if the facility or service was provided directly by the HMO; and
- (d) Would be available in a manner that is administratively feasible to the HMO.

4012.35 The general criteria set forth in Subsections 4012.36 through 4012.40 shall apply to applications proposing decreases in bed capacity or closure of services.

4012.36 If the Director determines that a proposed closure of beds or of a service does not comply with life safety, or licensure codes, the proposed closure shall satisfy the criterion of financial capability of the applicant to bring the facility, beds, or service into compliance with life safety and licensure standards. The standard for satisfying this criterion is by providing evidence and assurances that the applicant is financially incapable of taking actions necessary to bring the beds or service into code or standards compliance.

4012.37 When a proposed closure of beds or of a service is based on the applicant's claim of financial infeasibility of continued operations, the proposed closure shall satisfy the criterion for financial feasibility of continued operations. The standard for satisfying this criterion is by providing evidence and assurances that, despite operation of the facility in accordance with recognized management procedures and reasonable levels of efficiency, continued operation of the beds or service would produce continuing significant long term financial losses.

4012.38 For proposed bed reductions or service closures not subject to Subsections

4012.36 or 4012.37, the proposed reduction or closure shall satisfy the criterion for consistency of the proposed bed reduction or service closure with the goals of the HSP and AIP. The standard for complying with this criterion is by providing evidence and assurances that the project complies with the goals of the HSP and AIP.

4012.39 For proposed bed reductions or service closures not subject to Subsections 4012.36 or 4012.37, the proposed reduction or closure shall satisfy the criterion for degree of patient impact. The standard for complying with this criterion is by providing evidence and assurances that a proposed reduction or closure will not negatively affect consumers of health care services by causing any of the following:

- (a) Substantially increasing the cost of health care;
- (b) Substantially reducing the quality of health care;
- (c) Substantially reducing the availability of health care;
- (d) Substantially reducing the acceptability of health care;
- (e) Substantially reducing continuity of health care; or
- (f) Substantially reducing the accessibility of health care.

4013 FEES

4013.1 Pursuant to D.C. Official Code § 44-420(a), SHPDA shall collect application fees for a CON request. SHPDA may collect fees for data, analyses, and reports published by SHPDA. SHPDA shall also collect an annual user fee for private hospitals in lieu of a CON application fee. SHPDA may also establish user fees for other classes of facilities. All fees collected under this section shall be non-refundable.

4013.2 Pursuant to D.C. Official Code § 44-420(a), SHPDA may adjust user fees periodically to reflect changes in the Consumer Price Index. User fees stated in this section reflect changes in the Consumer Price Index through 2009. SHPDA may make further adjustments to the user fees by publishing notice of the revised fee in the *D.C. Register*, and the change shall become effective upon publication of the notice.

4013.3 The schedule of fees for application for CON and user fees shall be as follows:

- (a) The CON application fee shall be the greater of three percent (3%) of the proposed capital expenditure for a proposed project or five thousand dollars (\$5,000);

- (b) The annual user fees for private hospitals shall be four dollars (\$4.00) per inpatient admission; and
- (c) The CON application fee for a project receiving funds through the Medical Homes DC Initiative, operated by the District of Columbia Primary Care Association shall be five thousand dollars (\$5,000).

4013.4 SHPDA may adjust the annual user fee required of private hospitals under § 4013.3(b) to reflect changes in the Consumer Price Index issued by the Bureau of Labor Statistics by publishing the change in fee in the *D.C. Register*.

4013.5 The schedule of fees for data, analyses, and reports published by SHPDA shall be as follows:

- (a) RESERVED.
- (b) RESERVED.

4099 DEFINITIONS

4099.1 When used in Chapters 40 through 45 of this title, the following terms and phrases shall have the meanings ascribed:

Act—the Health Services Planning Program Re-establishment Act of 1996, effective April 9, 1997 (D.C. Official Code § 44-401 *et seq.*).

Acute long-term care—services provided by a hospital in a separate unit set aside for patients requiring hospital level care for periods longer than thirty (30) days.

Ambulatory care facility or clinic—

- (1) An institution, place, or building devoted primarily to providing health care services to outpatients through any organizational arrangement other than solely through the private practice of one (1) or more physicians acting as a sole practitioner or a group practice. A group practice shall not include any arrangement in which one (1) or more physicians are hired as employees, as contractors, or other comparable arrangement to provide health services. This term does not include facilities maintained by employers solely to provide first aid or primary health care services to their employee during the employee’s hours of work. This term does not include a health fair that continues for less than seven (7) days;
- (2) An entity that received federal grant support, a block grant, or other program for the operation of a community or neighborhood health center;

or

- (3) An entity that receives donations for providing health services to outpatients.

Ambulatory surgical facility—a facility that is not a part of a hospital that provides surgical treatment to patients not requiring hospitalization and that is licensed or proposed to be licensed as an ambulatory surgical treatment center by the District under the Health-Care and Community Residence Facility, Hospice and Home Care Licensure Act of 1983, effective February 24, 1984 (D.C. Law 5-48; D.C. Official Code § 44-501 et seq.).

Annual Implementation Plan or AIP—the annual plan prepared by SHPDA and SHCC to specify actions that will achieve the goals and objectives of the State Health Systems Plan.

Applicant—a person who consults with SHPDA before applying for a CON or a person who applies for a CON.

Certificate of Need or CON—the documentation demonstrating approval from SHPDA that is required before a person may offer or develop a new institutional health service or obligate a capital expenditure to obtain an asset.

Director—the Director of the SHPDA of the Department of Health.

Ex parte contact—an oral or written communication not on the official record where reasonable contemporaneous notice to all parties is not given.

Freestanding hemodialysis facility—a kidney disease treatment facility, not located within a hospital, that provides chronic maintenance hemodialysis services.

General hospital—an institution that primarily provides to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons, and that is licensed or proposed to be licensed as a hospital by the District government.

Health care facility or HCF—a private general hospital, psychiatric hospital, other specialty hospital, rehabilitation facility, skilled nursing facility, intermediate care facility, ambulatory care center or clinic, ambulatory surgical facility, kidney disease treatment center, freestanding hemodialysis facility, diagnostic health care facility, home health agency,

hospice, or other comparable health care facility that has an annual operating budget of at least five hundred thousand dollars (\$500,000). This term shall not include Christian Science sanitariums, operated, listed, and certified by the First Church of Christ Scientist, Boston, Massachusetts; the private office facilities of a health professional or group of professionals, where the health professional or group of health professionals provides conventional office services limited to medical consultation, general non-invasive examination, and minor treatment, or a health facility licensed or to be licensed as a community residence facility, or an Assisted Living Residence.

Health Maintenance Organization or HMO—a private organization that is a qualifying HMO under federal regulations or has been determined to be an HMO under 22 DCMR Chapters 40 through 45.

Health service—a medical or clinical related service, including a service that is diagnostic, curative, or rehabilitative, and those related to alcohol abuse, drug abuse, inpatient mental health services, home health care, hospice care, medically supervised day care, and renal dialysis. This term shall not include services provided by physicians, dentists, HMOs, and other individual providers in individual or group practice.

Health Systems Plan or HSP—the comprehensive health plan prepared by SHPDA and the SHCC according to the requirements of the Act.

Home health agency—a public agency or private organization, or a subdivision of an agency or organization, that is primarily engaged in providing skilled nursing services and at least one (1) other therapeutic service to individuals in their residences, that has at least one (1) employee in addition to the proprietor if the agency is a sole proprietorship. This term does not include an entity that provides only housekeeping services.

Inpatient—the provision of health care services over a period of twenty-four (24) consecutive hours or longer.

Intermediate care facility or ICF—an institution that provides, on a regular basis, health-related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility provides, but who, because of their mental or physical condition, require health-related care and services (above the level of room and board), that is licensed or proposed to be licensed as an intermediate care facility by the District government.

Other specialty hospital—an institution primarily engaged in providing to inpatients diagnosis and treatment for the limited category of illness or illnesses for which the institution is or proposes to be licensed as a

“special hospital” by the District government. The term does not include a psychiatric hospital, rehabilitation facility, or rehabilitation hospital.

Outpatient—the provision of health care services over less than twenty-four (24) consecutive hours.

Psychiatric hospital—an institution that primarily provides to inpatients, by or under the supervision of a physician, specialized services for the diagnosis, treatment, and rehabilitation of mentally ill and emotionally disturbed persons, that is licensed or proposed to be licensed as a hospital by the District government.

Rehabilitation facility or rehabilitation hospital—a facility that is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical and other services which are provided under competent professional supervision, and that, if it serves inpatients, is licensed or proposed to be licensed as a “special hospital” by the District government.

Skilled nursing facility or SNF—an institution or a distinct part of an institution that primarily provides to inpatients skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons, that is licensed or proposed to be licensed as a skilled nursing facility by the District government.

Year—unless otherwise indicated, any period of three hundred sixty-five (365) consecutive days.

CHAPTER 41 CERTIFICATE OF NEED REVIEW

4100 NEW HEALTH SERVICES

4100.1 Except for a new institutional health service offered solely for research, no person shall construct, develop, or otherwise establish a new institutional health service including a new health care facility, health care service, or home health or nursing service without first obtaining a CON. A person establishing a new institutional health service solely for research shall notify SHPDA in writing of its intent to do so and the purpose of the new institutional health service.

4100.2 The following shall be institutional health services for purposes of this title:

- (a) Acute medical-surgical services not otherwise specified;
- (b) Cardiac catheterization services;

- (c) Cardiac surgery services;
- (d) Coronary care services;
- (e) Computed tomography services;
- (f) Neonatal intensive care services;
- (g) Newborn services;
- (h) Obstetric services;
- (i) Pediatric services;
- (j) Pediatric cardiac surgery services;
- (k) Physical medicine and rehabilitation services;
- (l) Psychiatric care services, short-term;
- (m) Psychiatric care services, long-term;
- (n) Emergency medical services;
- (o) Physical therapy services;
- (p) Occupational therapy services;
- (q) Home health services;
- (r) Hospice care;
- (s) Diagnostic radiology and ultrasound services;
- (t) Radiation therapy services;
- (u) Burn services;
- (v) Ambulatory surgery services;
- (w) Primary care centers' services;
- (x) Alcoholism-chemical dependency services
- (y) Acute long-term services;

- (z) Skilled nursing services;
- (aa) Acute dialysis services, including inpatient hemodialysis and inpatient intermittent peritoneal dialysis;
- (bb) Outpatient staff-assisted in-facility chronic maintenance hemodialysis services;
- (cc) Outpatient self-care in-facility chronic maintenance hemodialysis services, including training;
- (dd) Outpatient self-care in-facility intermittent peritoneal dialysis services, including training;
- (ee) Training for home intermittent peritoneal dialysis;
- (ff) Training and follow-up services for continuous ambulatory peritoneal dialysis;
- (gg) Renal dialysis services based on dialysis technologies not otherwise specified;
- (hh) Renal transplantation services;
- (ii) New technology as determined by SHPDA;
- (jj) Transplant services; and
- (kk) Open heart surgery.

4100.3 The Director may periodically assess and update the list set forth in Subsection 4100.2, as warranted by changes in medical technology and practice, and may add a health service to the list when, in his or her judgment, a new medical technique is of a highly specialized nature.

4101 NEW HEALTH SERVICES DETERMINATIONS

4101.1 A person shall request a determination from SHPDA as to whether a new technique constitutes a new institutional health service subject to review before offering any new medical technique of a highly specialized nature not appearing on SHPDA list of health services.

4101.2 No person shall offer any new medical technique, other than for research or emergency purposes, before receiving a final determination from SHPDA that the technique does or does not constitute a new health service.

4101.3 The Director shall make a determination whether a medical technique constitutes a new health service within one hundred twenty (120) days after receiving the

request. SHPDA may request additional documentation from the person in support of the request to assist SHPDA in making its determination.

4102 CAPITAL EXPENDITURES

4102.1 Except for a capital expenditure made solely for research, no person shall make or obligate a capital expenditure for a health service or facility before first obtaining a CON if:

- (a) The capital expenditure is two million five hundred thousand dollars (\$2,500,000) or more;
- (b) The capital expenditure is for major medical equipment valued at one million five hundred thousand dollars (\$1,500,000) or more; or
- (c) The capital expenditure is for a single piece of diagnostic equipment for which the cost or value is two hundred fifty thousand dollars (\$250,000) or more.

4102.2 A person intending to make a capital expenditure solely for the purpose of research shall notify SHPDA of its intent in writing and describe the nature of the capital expenditure to be made for research purposes.

4102.3 For the purposes of this section, capital expenditure includes the cost of any studies, surveys, designs, plans, working drawings, specifications, or other services (including staff effort) associated with the capital expenditure.

4102.4 A capital expenditure unrelated to patient care valued at eight million dollars (\$8,000,000) or more, by an existing health facility shall require CON review unless the facility or activity is specifically exempted from CON review.

4102.5 A capital expenditure by a non-health facility component of a larger institution that also includes a hospital or other health facility or service (such as those made by a university or medical school that operates a hospital) shall not be treated as relating to the health service or facility unless either of the following applies:

- (a) Any part of the capital expenditure is made by or represents an obligation of the health facility or service component; or
- (b) The expenditure actually or potentially directly affects patient charges or the cost of providing care.

4102.6 An obligation for a capital expenditure shall be considered to be incurred by or on behalf of a health care facility:

- (a) On the date that a health care facility, or another entity on behalf of the

HCF, enters into a contract enforceable under law for the construction, acquisition, lease, or financing of a capital asset;

- (b) On the date that the governing board of the health care facility takes formal action to commit its own funds for a construction project undertaken by the HCF as its own contractor; or
- (c) On the date on which the gift is completed, when the property is donated.

4102.7 An obligation for a capital expenditure that is contingent on the issuance of a CON shall be considered not to be incurred until SHPDA issues the CON.

4102.8 The provisions of Subsection 4102.1 shall not limit any form of preliminary budget approval for inclusion in the budget by the applicant's administrative review authority.

4102.9 Budget inclusion shall be a prerequisite for submitting a complete application for a CON.

4103 MAJOR MEDICAL EQUIPMENT

4103.1 Except for the acquisition of major medical equipment solely for research, no person or HCF shall acquire (in whole or in part) through lease, rental, donation, or any comparable arrangement, or put into operation, major medical equipment (a single unit or system with related functions) without first obtaining a CON.

4103.2 A HCF acquiring major medical equipment solely for research shall notify SHPDA in writing of its intent to acquire the equipment and describe the use to be made of the major medical equipment.

4103.3 If major medical equipment is acquired by a lease or comparable arrangement, or any other type of transfer by two (2) or more persons acting in concert, and if the aggregate cost of the acquisition would be one million five hundred thousand dollars (\$1,500,000) or more, or two hundred fifty thousand dollars (\$250,000) or more for a single piece of diagnostic equipment, if the acquisition had been by purchase at fair market value, the acquisition shall be deemed an acquisition of major medical equipment requiring CON review, notwithstanding that the cost or value to each participating person of that acquisition may be less than the monetary threshold for major medical equipment.

4104 REVIEW OF PROPOSALS: BEDS

4104.1 No person shall increase, decrease, or redistribute among health service categories the bed capacity of a HCF by ten percent (10%) or ten (10) beds, whichever is less, in any two (2) year period.

4104.2 The distribution of bed types shall use the following categories:

- (a) Medical-surgical;
- (b) Coronary care;
- (c) Obstetrics-gynecology;
- (d) Obstetrics-gynecology;
- (e) Normal nursery and neonatal intermediate care;
- (f) Neonatal Intensive care;
- (g) Pediatrics;
- (h) Alcoholism, chemical dependency;
- (i) Rehabilitation;
- (j) Extended acute long-term care;
- (k) Medical-surgical or skilled nursing;
- (l) SNF;
- (m) ICF; and
- (n) Skilled nursing or intermediate care (swing in a facility licensed as both a SNF and ICF).

4104.3 A person may lawfully close a bed without obtaining a CON under the following circumstances:

- (a) A HCF has not staffed or otherwise held the bed ready for immediate use by patients for twelve (12) consecutive months; and
- (b) The bed, when taken together with the sum of all other beds closed and opened does not represent a net change of more than ten (10) beds or ten percent (10%) of the total number of beds authorized in the HCF or particular service during the twenty-four (24) month period preceding the closure.

4104.4 The date on which the HCF removes the last patient from a recognized unit shall begin the consecutive twelve (12) month period under Subsection 4104.3(a) for every bed in the unit proposed for closure.

4104.5 Reopening one (1) or more beds by re-staffing it and otherwise holding it ready for immediate use, while at the same time removing staff and otherwise removing the same or a similar number of other beds of the same general type from immediate use by patients shall not constitute the beginning of another consecutive twelve (12) month period.

4104.6 Rotating short-term suspensions of individual beds or units shall not be used to circumvent the consecutive twelve (12) month period specified in Subsection 4104.3(a).

4105 REVIEW OF PROPOSALS: NEW SERVICES

4105.1 No person shall offer an institutional health service by or through an HCF that was not offered by the same HCF on a regular basis within the twelve (12) month period before the time the service would begin without first obtaining a CON.

4105.2 For purposes of this section, the term “offer a service on a regular basis” shall mean being staffed and otherwise prepared to deliver the service at all times or on a regularly scheduled basis. Inability to deliver a service as scheduled for reasons beyond the control of the provider in emergency situations of short duration shall not affect a provider’s offering of a service on a regular basis.

4105.3 A service offered “through” an HCF or an HMO includes a service that is offered to a substantial extent (as determined by SHPDA) on behalf of that institution by others and not offered physically in the institution subject to review.

4105.4 A service offered at a different facility shall not satisfy the requirement that the service has been offered on a regular basis.

4106 REVIEW OF PROPOSALS: RENAL DIALYSIS

4106.1 No person shall increase the number of renal dialysis stations in an HCF or health service or move stations from one HCF to another without first obtaining a CON.

4106.2 For purposes of this section, a “renal dialysis station” means a station certified for participation in the Federal End Stage Renal Disease (ESRD) Program under Medicare, or an equivalent station.

4106.3 Renal dialysis stations shall be categorized into the following types, with each type considered a separate health care service:

- (a) Acute dialysis services, including inpatient hemodialysis and inpatient intermittent peritoneal dialysis;
- (b) Outpatient staff-assisted, in-facility, chronic maintenance hemodialysis services;

- (c) Outpatient self-care, in-facility, chronic maintenance hemodialysis services, including training;
- (d) Outpatient self-care, In-facility, Intermittent peritoneal dialysis services, including training;
- (e) Training for home intermittent peritoneal dialysis; and
- (f) Any other dialysis service approved by the Director.

4106.4 An increase in renal dialysis services not involving stations may be subject to CON review under other provisions of Chapters 40 through 45 of this title.

4107 REVIEW OF PROPOSALS: CLOSURES

4107.1 No person shall permanently close a health care facility or health service, without notifying SHPDA, in writing and obtaining its approval.

4107.2 For purposes of this section, the phrase “permanently close a health care or service” means removing staff or equipment necessary to operate a facility or service for a period longer than twelve (12) consecutive months.

4107.3 Removing equipment shall include allowing equipment that is not operational to remain in place.

4107.4 The date of the removal for inpatient facilities is the date that the last patient is removed from the facility and shall be the beginning of the twelve (12) consecutive month period under Subsection 4107.2.

4107.5 An HCF shall maintain nurse staffing schedules, daily patient census, and other relevant records so that compliance with the requirements of this section may be readily demonstrated, and shall permit SHPDA inspection of those records upon request.

4107.6 A person proposing to permanently close an HCF or health service shall notify SHPDA of the proposed closing not later than ninety (90) days before the proposed closing.

4107.7 The notice required by Subsection 4107.6 shall include the following information:

- (a) A description of what is to be closed;
- (b) The name of the owner of the HCF or health service to be closed;
- (c) The expected date of closure;

- (d) The number, type, and condition of patients affected;
- (e) The provisions that the provider is making for the continuing care of the affected patients; and
- (f) A detailed explanation for the closure.

4107.8 SHPDA shall provide assistance for an orderly transition of patient care to the extent possible.

4108 ACQUISITIONS

4108.1 No person shall acquire an existing HCF by purchase, lease, or other arrangement to acquire effective control over a facility without first obtaining a CON.

4108.2 For purposes of this section, the phrase “acquire effective control” includes:

- (a) A transfer, assignment or other disposition of fifty per cent (50%) or more of the stock, voting rights thereunder, ownership interest, or operating assets of the corporation or entity;
- (b) A transaction resulting in a person, or a group of persons acting in concert, owning or controlling, directly or indirectly, fifty per cent (50%) or more of the stock, voting rights thereunder, ownership interest, or operating assets of the corporation or entity;
- (c) A transaction resulting in a person, or a group of persons acting in concert, having the ability to elect or cause the election of a majority of the board of directors of a corporation or entity; or
- (d) A conversion that results in selling, transferring, leasing, exchanging, conveying, or otherwise disposing of, directly or indirectly, all the assets or a material amount of the assets of a nonprofit HCF to a for-profit entity, whether a corporation, mutual benefit corporation, limited liability partnership, general partnership, joint venture, or sole proprietorship, including an entity that results from, or is created in connection with, the conversion.

4109 HEALTH MAINTENANCE ORGANIZATIONS

4109.1 A Health Maintenance Organization (HMO), or combination of HMOs, shall obtain a CON before undertaking any activity for which a CON is required unless it applies for and receives an exemption from SHPDA under this section.

4109.2 In its application for exemption, the HMO, or combination of HMOs, shall

provide information to demonstrate the following:

- (a) The facility in which the service will be provided is or will be geographically located in a place that is reasonably accessible to the enrolled individuals; and
- (b) At least seventy-five percent (75%) of the patients who can reasonably be expected to receive the health service will be individuals enrolled in the HMO (or HMOs in combination).

4109.3 SHPDA shall grant a HMO an exemption under this section after a review of not more than fifteen (15) days if it has not begun to provide health care services on the date an application is submitted for an exemption and it satisfies the criteria in Subsection 4109.2.

4109.4 Any decision by SHPDA to approve or deny an application for an HMO exemption shall be based solely on the record established in the administrative proceedings held with respect to the application.

4109.5 No exemption shall be granted solely because SHPDA failed to reach a decision within the fifteen (15) day review period.

4199 DEFINITIONS

4199.1 The provisions of Section 4099 of this title, and the definitions set forth in that section shall apply to this chapter.

CHAPTER 42 APPLICATION FOR CERTIFICATE OF NEED REVIEW

4200 SUBMISSION OF APPLICATIONS

4200.1 An applicant shall submit an application for a CON in writing on a form prescribed by SHPDA. The form shall contain the information that SHPDA uniformly prescribes and publishes as requirements for a CON.

4200.2 An application for major medical equipment or a capital expenditure shall specify the applicant's proposed timetable to make that service or equipment available and to complete the project, as well as other information SHPDA shall require for evaluating the application under the appropriate review criteria, the State Health Plan, and the requirements of the District of Columbia Health Services Planning Program Re-Establishment Act of 1996, (D.C. Official Code § 44-401 *et seq.*).

4200.3 SHPDA shall use a single form for each type of application, except transfer of ownership, even though not all questions on the form may be relevant for a particular type of application. SHPDA, in a pre-application meeting between the applicant and an assigned SHPDA staff member, shall specify for each applicant

the questions that require responses for that application.

- 4200.4 If SHPDA determines that an application is incomplete, and that additional information is needed to evaluate the application, SHPDA shall request additional information from the applicant pursuant to the requirements of Subsections 4200.5 through 4200.7. The information requirements may vary according to the purpose of the review or the type of health service being reviewed.
- 4200.5 A request from SHPDA for information from the applicant pursuant to § 4200.4 and in connection with a CON review shall be in writing and limited to the information that is necessary for SHPDA and SHCC to perform their reviews.
- 4200.6 SHPDA shall notify the applicant in writing when it has determined that the application is complete.
- 4200.7 SHPDA may review an application that has not been determined to be complete if the applicant has declined to provide further information and shall base its findings on the information available from the applicant that will demonstrate that the application complies with the HSP or the applicable criteria and standards for the service or HCF.

4201 RESERVED

4202 REVIEW PROCESS

- 4202.1 SHPDA shall begin a review at the beginning of one (1) of twelve (12) review cycles to be held each calendar year.
- 4202.2 The regular or expedited review cycles for an application shall be determined by the day on which the application is complete or deemed complete upon refusal of the applicant to supply further information. The review cycle for a CON application shall begin on the twentieth (20th) day of each month, or on the first (1st) business day following, if that day falls on a weekend or holiday. The review period for a regular review shall end ninety (90) days after the beginning of the review cycle. The review period for an expedited review shall end thirty (30) days after the beginning of the review cycle.
- 4202.3 SHPDA shall complete the review within the time period specified in Subsection 4202.2 unless the applicant requests, and SHPDA approves, an extended review period.
- 4202.4 If SHPDA fails to approve or deny an application within the applicable time period, the applicant may, within a reasonable period of time following expiration of the applicable time period, bring an action in Superior Court to require SHPDA to approve or deny the application. No CON shall be issued solely because SHPDA failed to reach a decision within the specified review period.

- 4202.5 An applicant may request in writing to SHPDA that either the regular ninety (90) day review period or the thirty (30) day expedited review period be extended for up to twelve (12) months. SHPDA may grant an extension of the review period for a period of time that is not longer than the applicant's request.
- 4202.6 For a batched review, a request for extension of the review period shall affect each application in the batched review. The request for extension of time to complete the review shall not be granted unless there is agreement to the extension of time from each applicant involved in that particular batched review.
- 4202.7 If SHPDA denies an extension of time for a batch review, the requesting party may:
- (a) Go forward with the batch review;
 - (b) Request review of the application at a later date; or
 - (c) Withdraw the application.
- 4202.8 If SHPDA or SHCC requires additional information necessary to performing the review after the review period has begun, an applicant shall have fifteen (15) days to provide the information. The applicant's response time shall extend the ninety (90) day review period.
- 4202.9 If SHPDA finds it impractical to complete a review within ninety (90) days, SHPDA may extend the review period for the following administrative reasons:
- (a) When an application modification is extensive but not so substantial as to require withdrawal and resubmission under Subsections 4203.1 and 4203.3;
 - (b) When the SHCC or a SHCC committee requests that SHPDA perform additional staff analysis of an application modified as described in paragraph (a) of this subsection and in accordance with § 4202.9 after the staff has substantially completed the initial analysis;
 - (c) When there is a sudden or unexpected major disruption of normal SHPDA operations, including those resulting from utility failure, natural disasters, and equipment failure; or
 - (d) When a public hearing is held during the review period.
- 4202.10 When there is an administrative extension of the review process as provided in Subsection 4202.9, SHPDA shall complete the review as expeditiously as is reasonable in the circumstances, and shall inform the applicant and other affected

persons of the projected timetable for completing the review.

4203 SUBSTANTIAL MODIFICATION OF APPLICATION

4203.1 When an applicant proposes a substantial modification of a CON application the applicant may be required to withdraw the original application and submit a new application reflecting the modifications.

4203.2 The new application constitutes a wholly separate application and is subject to all elements of the review process, including submission of a Letter of Intent for the new application. SHPDA shall waive the sixty (60) day waiting period following the submission of a Letter of Intent for the submission of a new application when the application results from substantial modification of an original application.

4203.3 For purposes of this section, the term "substantial modification" includes:

- (a) A change in the location of the facility to a different Advisory Neighborhood Commission, service, or the type of facility or service;
- (b) A change in the proposed capital expenditure budget of thirty percent (30%) or more;
- (c) A change increasing or decreasing patient load or units of service by forty percent (40%) or more from the capacity originally proposed; or
- (e) A change in the ownership or effective control of the entity seeking to obtain a CON that, if the entity already held a valid CON, would cause the revocation of the CON under Section 4009 of this title.

4204 MORATORIUM ON APPLICATIONS

4204.1 If SHPDA determines that it needs additional time to develop and adopt CON application review criteria and standards for specific types of facility or service, SHPDA may impose a moratorium on consideration of all applications for that specific type of facility or service for which a review has not begun.

4204.2 For the purposes of this section, development and adoption of CON application review criteria and standards shall include development and adoption of, or revision of, the HSP if the HSP will contain the required criteria and standards.

4204.3 A moratorium imposed pursuant to Subsection 4204.1 shall last for not more than one hundred twenty (120) days in a twelve (12) month period.

4204.4 SHPDA shall give general notice in a newspaper of general circulation within the District of Columbia and on the Department of Health website of the terms and conditions of the moratorium within fifteen (15) days after a decision to declare a

moratorium on a specific type of facility or service. SHPDA shall also give specific notice within 15 days to:

- (a) The SHCC; and
- (b) Every person who has submitted a Letter of Intent.

4299 DEFINITIONS

4299.1 The provisions of § 4099 of Chapter 40 of this title, and the definitions set forth in that section, shall apply to this chapter.

CHAPTER 43 REVIEW SCHEDULES

4300 GENERAL PROVISIONS

4300.1 An application that SHPDA determines to be complete by the tenth (10th) day of any month shall be reviewed during the review that begins on or after the twentieth (20th) day of the same month.

4300.2 An application that SHPDA determines to be complete after the tenth (10th) day of any month shall be reviewed during the next regular review that begins on or after the twentieth (20th) day of the following month.

4300.3 SHPDA shall conduct batched reviews for the types of applications specified in the following schedule:

APPLICATION TYPE	MONTHS
Alcoholism/chemical dependency services	January, July
Diagnostic radiology and ultrasound services	February, August
Home health services	April, October
Renal disease services	March, September

4301 REGULAR AND EXPEDITED REVIEWS

4301.1 SHPDA shall review each CON application by either a regular or an expedited process.

4301.2 Except as provided in Subsection 4301.3, the expedited review process shall be used for each application that proposes major medical equipment or a new institutional health service for which there is an explicit finding of need in the HSP.

4301.3 SHPDA shall not conduct an expedited review for an otherwise qualified project related to a service for which the HSP states there is an excess of capacity or that

has not been included in the HSP.

- 4301.4 SHPDA shall review an application through the regular review process at the request of an applicant even though the application qualifies for expedited review.
- 4301.5 The Director shall render a written decision regarding a request for expedited review. A person may request reconsideration of the decision in writing upon providing good cause. A request for reconsideration shall not be referred to the SHCC.
- 4301.6 The results of an expedited review shall be reported to the SHCC at the next regularly scheduled SHCC meeting.
- 4301.7 SHPDA shall use the same criteria and standards that apply to projects reviewed by the regular process for an application that will receive expedited review, and designation for expedited review shall in no way imply automatic approval of the application by SHPDA.
- 4301.8 The expedited review process differs from the regular review process as follows:
- (a) An application reviewed through the expedited process shall not be referred to the SHCC for review and comment before the Director approves or denies an application; and
 - (b) An expedited review shall be completed within thirty (30) days after receipt of a completed application.

4302 PUBLIC HEARINGS

- 4302.1 SHPDA may call a public hearing on its own initiative on an application during the first thirty (30) days of the CON application review period.
- 4302.2 SHPDA shall also call a public hearing at the request of an affected person. The request for public hearing shall be in writing and submitted no later than thirty (30) days after the beginning of the review period or the date of notice required pursuant to Subsection 4302.6, whichever is later.
- 4302.3 For the purposes of this section, an affected person includes:
- (a) The applicant;
 - (b) A person who participated in the proceedings before SHPDA or the Office of Administrative Hearings;
 - (c) A person who is a recipient of the types of services proposed in the CON application;

- (d) A person who resides within the boundaries of the Advisory Neighborhood Commission where the facility or service will be located or provide services;
- (e) An HCF or HMO located in the health service area in which the project is proposed to be located that provides services similar to the services of the facility under review;
- (f) An HCF or HMO that, prior to SHPDA's receipt of the proposal being reviewed, has formally indicated an intention to provide similar services in the future;
- (g) A third party payer who reimburses an HCF for services in the health service area in which the project is proposed to be located; and
- (h) A person who regularly uses an HCF within the geographic area where the facility or service is to be located or provided.

4302.4 An affected person shall have the right to be represented by counsel and to present oral or written testimony and evidence relevant to the matter that is the subject of the public hearing.

4302.5 SHPDA shall maintain a verbatim electronic record of the public hearing.

4302.6 RESERVED

4302.7 The notice shall include:

- (a) The name of the applicant;
- (b) The service to be provided;
- (c) The proposed location of the service to be provided;
- (d) The date, time, and location of the meeting;
- (e) The planned hearing agenda; and
- (f) A description of matter to be discussed.

4302.8 SHPDA shall hold the public hearing no sooner than fourteen (14) days after the date of the notice of the public hearing.

4302.9 SHPDA shall not charge a fee to hold a public hearing.

4303 STATEWIDE HEALTH COORDINATING COUNCIL

- 4303.1 Unless SHPDA has determined that it cannot complete a regular review within ninety (90) days for a reason specified in § 4200 or the Applicant has requested postponement of the review, SHPDA shall forward to the members of the appropriate SHCC committee or the entire SHCC, as directed by the SHCC, a staff analysis of an application being reviewed under the regular review process no later than fifty-five (55) days after the beginning of the regular review process.
- 4303.2 SHPDA analysis under Subsection 4303.1 shall include positive and negative aspects of the application in relation to the HSP and adopted criteria.
- 4303.3 After SHCC receives SHPDA staff analysis, the SHCC shall review and comment on the application pursuant to the SHCC by-laws.
- 4303.4 A SHCC member who has a conflict of interest concerning an application shall follow the provisions of the SHCC by-laws regarding conflicts of interest.
- 4303.5 During the SHCC review and before the SHCC adopts a formal recommendation, the SHCC may require a public hearing on the application.
- 4303.6 The Director shall schedule a public hearing required by the SHCC pursuant to Subsection 4303.5 pursuant to the procedures specified in Section 4302. The Director shall provide notice for meetings of the SHCC according to the procedures set forth in Subsections 4302.5 through 4302.7. The Director shall make the minutes and hearing record available according to the requirements set for in Subsection 4302.10.
- 4303.7 If the SHCC fails to make a recommendation concerning an application within eighty (80) days after receiving the SHPDA staff analysis, the Director may render a decision on the CON application without the advice of the SHCC.
- 4303.8 The Director shall consider a timely made recommendation of the SHCC in making a decision.

4304 INSPECTION OF RECORDS

- 4304.1 Except as provided in Subsection 4304.3, a person may inspect a CON application and other information contained in SHPDA project files during regular business hours.
- 4304.2 A person may receive a copy of a document subject to inspection upon the payment of a reasonable fee to cover the cost of reproduction.
- 4304.3 A person shall not inspect or copy a portion of a CON application or other document related to a CON application that contains detailed technical

descriptions of proprietary financial information, security systems, medical records systems, or controlled substance storage systems if SHPDA designates that portion of an application as “restricted”.

4304.4 SHPDA may designate a portion of a CON application as “restricted” by the following procedures:

- (a) The applicant shall make a written request to SHPDA to restrict the material at the time the applicant submits the application;
- (b) SHPDA shall maintain the material to be categorized as “restricted” separate from the remainder of the CON application retained in SHPDA files until it renders a decision about whether the material should be restricted;
- (c) The SHPDA staff person in charge of the CON review shall make a determination whether the information in question would provide information for a person to violate the security of the system in question or reveal proprietary information that would give a competitor an unfair advantage; and
- (d) If SHPDA agrees to restrict material, the applicant shall provide a non-restricted and non-technical summary of the “restricted” material and submit the original information printed on paper, other than white or blue, and marked on each page at top and bottom with the statement “Restricted Security System Information; Not for Public Inspection.”

4304.5 If the applicant disagrees with the SHPDA staff person in charge of the CON review concerning a request for classifying material as “restricted,” the applicant may appeal the decision by making a written request for a meeting to review the matter with the Director, who shall make the final decision.

4304.6 An applicant shall not submit medical records that identify individual patients to SHPDA. Any patient record the applicant provides to SHPDA that includes personal identifying information, such as copies of driver’s licenses, social security cards, that is submitted inadvertently shall not be available for public inspection.

4305 EX PARTE CONTACTS

4305.1 There shall be no *ex parte* contacts between:

- (a) A person acting on behalf of the applicant or a CON holder, or any person opposed to or in support of issuing or modifying a CON or in favor of withdrawing a CON; and

(b) A person in SHPDA who exercises responsibility for reviewing the application or withdrawing the application.

4305.2 There shall be no oral *ex parte* contacts after the commencement of a hearing for an application for a CON, a proposed modification, or withdrawal of a CON and until SHPDA makes a decision. An interested person, including the applicant, may make written *ex parte* contacts to the SHPDA after commencement of the hearing if SHPDA keeps the hearing record open after the hearing.

4305.3 When SHPDA will not hold a hearing for a CON, a proposed modification, or a withdrawal, there shall be no oral *ex parte* contacts after the conclusion of the project review committee meeting for that application. An interested person, including the applicant, may make written *ex parte* contacts after the conclusion of the project review committee meeting if the project review committee allows additional time for an interested party to supply additional information.

4305.4 If a SHPDA staff person or SHCC member receives an *ex parte* contact prohibited under this section, he or she shall, within forty-eight (48) hours after first having reason to believe that there was a prohibited contact, prepare and deliver a written statement summarizing the substance of an oral contact or the written communication, or a copy, to the Director's designee, or deliver to the person the Director designates.

4305.5 The Director or his or her designee shall make the statements or contacts available for inspection by placing them in a file separate from the public record of the application or proposed withdrawal under review.

4305.6 If a member of SHCC occupies an employment, fiduciary, consulting, or other similar relationship (as described in the SHCC by-laws provision governing conflict of interest) with an applicant or a CON holder, the SHCC member shall be considered to be acting on behalf of the applicant or CON holder; and any contact between the SHCC member and SHPDA staff, Director, or other SHCC members occurring in the period specified in Subsection 4305.2 shall be subject to the *ex parte* contacts prohibition of this section, provided that the contacts are related to the matter in question.

4305.7 For purposes of this section, the phrase "SHPDA staff" shall include the Director, staff, and the SHCC.

4305.8 A request for information concerning the status of a review made in accordance with Section 4201 shall not be considered an *ex parte* contact.

4306 CLOSING THE PROJECT RECORD

4306.1 The record for a decision on issuing or modifying a CON shall close at the end of the second (2nd) business day following the meeting of a Committee of the SHCC

at which the Committee makes the initial recommendation on the application; provided, that the record shall include those proceedings of the SHCC during which the application was considered, concluding with the final SHCC vote taken on the application.

4306.2 When SHPDA conducts an expedited review the record shall close five (5) business days before the date of decision.

4306.3 The Director may order that the record remain open for a longer period of time if the Director determines that keeping the record open is necessary to ensure an adequate record.

4306.4 The SHCC and the Director shall not consider information received from a person after the date specified in the notice (unless the Director extends the record) to make a recommendation or render a decision on an application.

4307 CONSIDERATIONS AND CRITERIA FOR REVIEW

4307.1 SHPDA and the SHCC, shall develop, adopt, and use general criteria and standards set forth in Section 4012 of this title and the specific considerations and criteria in this section to conduct a CON review. The applicant shall bear the burden of producing evidence and assurances sufficient to persuade the Director that the applicant can satisfy the requirements of each applicable criterion or standard.

4307.2 SHPDA shall evaluate an HMO, an ambulatory care facility, or HCF that is controlled, directly or indirectly, by an HMO or combination of HMOs, by the criteria and considerations set forth in Subsection 4307.15.

4307.3 A review may consider the relationship between the health services being proposed and the applicable AIP and HSP. Each decision of SHPDA, or the appropriate judicial or administrative review body, to issue a CON shall be consistent with the HSP, except in emergency circumstances that pose an imminent threat to public health.

4307.4 A review may consider the availability of less costly or more effective alternative methods of providing the services to be offered, expanded, reduced, relocated, or eliminated.

4307.5 A review may consider the immediate and long-term financial feasibility of the proposal, and the probable impact of the proposal on the costs of and charges for providing health services by the person proposing the service.

4307.6 A review may consider the need that the population served or to be served has for the services proposed to be offered or expanded, and the extent to which all residents of the area, particularly low income persons, racial and ethnic

minorities, women, persons with disabilities, the elderly, or other underserved groups, are likely to have access to those services.

- 4307.7 A review may consider the contribution of the proposed service in meeting the health related needs of members of medically underserved groups that have traditionally experienced difficulties in obtaining equal access to health services (such as low income persons, racial and ethnic minorities, women, and persons with disabilities), particularly those needs identified in the applicable AIP and HSP as deserving priority.
- 4307.8 SHPDA may consider the following for the purpose of determining accessibility of the proposed service:
- (a) The rate at which medically underserved populations currently use the applicant's services as compared to the percentage of the population in the applicant's service area that is medically underserved, and the rate at which medically underserved populations are expected to use the proposed services;
 - (b) The applicant's performance with meeting its obligation, if any, under any applicable federal and District regulations requiring the applicant to provide uncompensated care, community service, or access by minorities, and persons with disabilities to programs receiving Federal financial assistance (including the existence of any civil rights access complaints against the applicant);
 - (c) The rate at which the applicant serves Medicare, Medicaid, District program and medically indigent patients; and
 - (d) The extent to which the applicant offers a range of means for a person to access its services (*e.g.*, outpatient services, admission by house staff, admission by personal physicians).
- 4307.9 A review may consider the relationship of the services proposed to be provided to the existing health care delivery system.
- 4307.10 A review may consider the availability of resources (including health personnel, management personnel, and funds for capital and operating needs) for providing the services proposed to be provided and the need for alternative uses for those resources as identified by the applicable AIP and HSP.
- 4307.11 A review may consider the relationship of the health services proposed to be provided to ancillary or support services.
- 4307.12 A review may consider the effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area

where the services are to be provided.

4307.13 A review may consider the special needs and circumstances of those entities that provide a substantial portion of their services or resources, or both, to individuals not residing in the District or in an adjacent health service area. Those entities may include medical and other health professions schools, multidisciplinary clinics, and specialty centers.

4307.14 A review may consider the special needs and circumstances of HMOs. Those needs and circumstances shall be limited to the following:

- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health services proposed to be provided by the organization; and
- (b) The availability of the new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner that is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, SHPDA shall consider only whether the services from these providers would meet the following requirements:
 - (1) The services shall be available under a contract of at least five (5) years' duration;
 - (2) The services shall be available and conveniently accessible through physicians and other health professionals associated with the HMO (such as, whether physicians associated with the HMO have or will have full staff privileges at a non-HMO hospital);
 - (3) The services shall cost no more than if the services were provided by the HMO; and
 - (4) The services shall be available in a manner that is administratively feasible to the HMO.

4307.15 A review may consider the special needs and circumstances of biomedical and behavioral research projects that are designed to meet a national need and for which local conditions offer special advantages.

4307.16 A review of a construction project may consider the following:

- (a) The costs and methods of the proposed construction, including the costs and methods of providing energy;
- (b) The probable impact of the construction project under review on the costs

of providing health services by the applicant and on the costs and charges to the public of providing health services by other persons; and

(c) Compliance with applicable General Services' Administration guidelines.

- 4307.17 If proposed health services are to be available in a limited number of facilities, a review may consider the extent to which the health professional schools in the area will have access to the services for training purposes.
- 4307.18 A review may consider the special circumstances of an HCF with respect to the need for conserving energy.
- 4307.19 A review may consider the effect of competition on the supply of the health services being reviewed.
- 4307.20 A review may consider improvements or innovations in financing and delivering health services that foster competition and serve to promote quality assurance and cost effectiveness.
- 4307.21 A review may consider the efficiency and appropriateness of using existing services and facilities similar to the health services or facilities proposed to be provided.
- 4307.22 A review may consider the quality of care provided by existing facilities for a review of existing services or facilities.
- 4307.23 When an osteopathic or allopathic facility applies for a CON to construct, expand, or modernize an HCF, acquire major medical equipment, or add services, SHPDA may consider the need for that construction, expansion, modernization, acquisition of equipment, or addition of services based on the need for and the availability in the community of services and facilities for osteopathic and allopathic physicians and their patients. SHPDA may consider the application in terms of its impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.
- 4307.24 Criteria used for reviews in accordance with this section may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed.
- 4307.25 SHPDA may adopt or revise review criteria and standards for all applications or particular types of applications.
- 4307.26 SHPDA may establish or revise criteria and standards by including them in an adopted HSP.

4307.27 The criteria and standards adopted by SHPDA under Subsections 4307.25 and 4307.27 shall be incorporated in this title by reference.

4308 REVIEW DECISIONS

4308.1 The Director's decision to approve, deny, modify, or revoke a CON shall be in writing and shall be based on the following:

- (a) The review conducted pursuant to the Act and rules promulgated pursuant to the Act; and
- (b) The record established in an administrative proceeding related to a CON application review, reconsideration, or a SHPDA proposal to revoke or modify a CON application. For the purposes of this section the record shall include SHPDA staff research, testimony from a public hearing, and the information the applicant has provided.

4308.2 The written decision shall state the findings of fact related to the CON, including:

- (a) Whether the project is needed;
- (b) Whether the project will meet SHPDA's CON application review criteria and standards; and
- (c) Whether the applicant has complied or will be able to comply with uncompensated care requirements.

4308.3 SHPDA shall provide a copy of the written decision to the applicant and make a copy available to any other person upon request.

4308.4 If SHPDA approves the CON application the CON shall constitute the decision document.

4308.5 The Director shall not issue a CON unless the Director finds that the applicant has satisfied all of the requirements specified in Subsection 4308.2.

4309 NOTIFICATION OF REVIEW DECISIONS

4309.1 The Director shall notify the applicant of a review decision by issuing a CON or notifying the applicant by regular mail of findings denying the CON application.

4309.2 The Director shall provide the notice required by this section no later than the end of the review period, including any extension, established for the application.

4310 RECONSIDERATION OF REVIEW DECISIONS

- 4310.1 An affected person may request reconsideration of the review decision within thirty (30) days after the date of decision.
- 4310.2 The Director shall grant a request for reconsideration and shall hold a public hearing, if good cause is shown.
- 4310.3 For purposes this section “good cause” may be demonstrated as follows:
- (a) By presenting significant and relevant information not previously considered by SHPDA. Information that could have been presented during the course of review with reasonable diligence shall not be considered good cause for the purpose of this section;
 - (b) By demonstrating that there has been a significant change in a factor or circumstance the Director relied on to reach a review decision. Those factors may include the opening or closure of other facilities, changes in reimbursement policies of major third party payers, or changes in SHPDA’s criteria or standards or the HSP after the date of the review decision (but before expiration of the period to request reconsideration);
 - (c) By demonstrating that SHPDA materially failed to follow its review procedures as specified in the Act and this title. A “material failure” is one that may reasonably be believed to have affected the outcome of the Director’s review decision, that prevented the presentation of relevant information in time to be considered by the Director, or that involves an alleged violation of the prohibition on *ex parte* contacts specified in D.C. Official Code § 44-409(i); or
 - (d) By presenting other information that leads the Director to conclude that “good cause” is shown and a public hearing for reconsideration is in the public interest.
- 4310.4 If the Director finds good cause and grants reconsideration, the Director shall convene a public hearing within forty-five (45) days after a finding of good cause.
- 4310.5 The Director shall give notice of the hearing to the person requesting the hearing, the applicant for the CON in question, SHCC, and the general public.
- 4310.6 Notice of the public hearing shall be published in a newspaper of general distribution within the District.
- 4310.7 There shall be no *ex parte* contacts between any party and any member of SHPDA staff or SHCC related to the decision after the reconsideration hearing adjourns.

- 4310.8 A reconsideration public hearing is an informational hearing at which the CON applicant and any other person may submit oral or written testimony. The hearing is not a “contested case” hearing as that term is defined in D.C. Official Code § 2-502.
- 4310.9 A person proposing to give oral testimony at a public hearing for reconsideration (except the person requesting the hearing and the applicant or CON holder being reconsidered) shall schedule testimony with SHPDA at least one (1) business day before the hearing.
- 4310.10 A person who does not schedule oral testimony in advance shall be permitted to testify after all scheduled testimony has been presented.
- 4310.11 The person who requested reconsideration and the CON holder (if different from the person requesting reconsideration) shall each have one (1) hour to make a presentation. One (1) or more persons may present testimony on behalf of the applicant or the person who requested the reconsideration.
- 4310.12 Any other person or group shall be permitted to present oral testimony for up to ten (10) minutes.
- 4310.13 A member of SHPDA staff may address questions, at the discretion of the hearing officer, to a person presenting oral testimony.
- 4310.14 The time spent asking and responding to questions shall not count against the time limit of the person testifying.
- 4310.15 A person may submit written testimony to SHPDA before the hearing, at the hearing, or at any time before the hearing record closes.
- 4310.16 The hearing officer may close the record at the end of all oral testimony or hold the record open for a period of time not to exceed fourteen (14) days following the end of oral testimony.
- 4310.17 The Director or the hearing officer may, under special circumstances, extend the time limits for presentations prescribed in this section.
- 4310.18 The Director may limit the scope of the hearing as follows:
- (a) To the matters for which “good cause” was demonstrated in the reconsideration request;
 - (b) To issues of substantial progress or justification for lack of progress for a CON proposed to be withdrawn because of lack of progress; or

(c) To evidence of subsequent occurrences or information not previously available.

4310.19 SHPDA shall maintain a verbatim record of the hearing by making a sound recording or by making a transcription of the proceeding.

4310.20 SHPDA shall make a copy of the recorded hearing available upon payment of a reasonable fee to cover the cost of duplication.

4310.21 The Director shall issue a written decision, including findings of fact and conclusions of law, within thirty (30) days following the close of the hearing record.

4310.22 The Director may affirm, modify, or reverse the original SHPDA decision.

4310.23 The Director's decision shall constitute the final decision of SHPDA for all purposes.

4311 APPEAL OF REVIEW DECISIONS

4311.1 The Director's finding regarding a showing of "good cause" and the final decision resulting from a reconsideration review may be further appealed to the Office of Administrative Hearings by any person directly affected, including the applicant, the person who requested reconsideration, previously appearing parties, and the SHCC, within fifteen (15) days of the date of Director's finding or decision.

4311.2 A person adversely affected by a SHPDA decision may appeal the decision to the District of Columbia Court of Appeals after exhausting all administrative remedies including an appeal to the Office of Administrative Hearings.

4312 APPLICATION FEES

4312.1 Notwithstanding any other provision of Chapters 40 through 45 of this title, SHPDA shall not accept an application for CON review until the applicant first pays a non-refundable application fee in the amount specified in D.C. Official Code § 44-420(a). Acceptable forms of payment include a certified check or money order for the application fee made payable to the "D.C. Treasurer".

4312.2 A CON holder shall not be required to pay an application fee for an extension of a CON pursuant to Section 4007. A CON holder seeking extension beyond a fourth (4th) year, except for an administrative extension, shall submit a new CON application pursuant to Subsection 4007.14 and pay the applicable fee.

4312.3 An applicant shall not pay an application fee after withdrawing and resubmitting an application as a result of a substantial modification of an application pursuant to Section 4203, provided that the new application is submitted to SHPDA and

judged to be complete by SHPDA within six (6) months of the date of withdrawal. If the applicant fails to re-submit an application within six (6) months, the application shall be deemed void, and any further request for CON review shall require the payment of a new application fee. If the resubmitted application requires a fee higher than that charged for the initial (withdrawn) application, the applicant shall pay the difference between the fee previously paid and the fee that would apply if the resubmitted application had been originally submitted.

4399 DEFINITIONS

4399.1 The provisions of § 4099 of Chapter 40 of this title, and the definitions set forth in that section, shall apply to this chapter.

CHAPTER 44 UNCOMPENSATED CARE

4400 GENERAL PROVISIONS

4400.1 This chapter implements the requirements of the District of Columbia Health Services Planning Program Re-Establishment Act of 1996 (Act), effective April 9, 1997 (D.C. Law 11-191; D.C. Official Code § 44-401 et seq.), for the provision by health care facilities of uncompensated care as a condition of holding a Certificate of Need (CON).

4400.2 As a condition for issuance of a CON to a health care facility or health service that operates on a payment for services rendered basis, the health care facility or health service shall provide uncompensated care in an amount not less than three percent (3%) of the health care facility's or health service's annual operating expenses, less the amount of reimbursements it receives from Titles XVIII and XIX of the Social Security Act (Medicaid and Medicare), without regard for contractual allowances. In addition, the health care facility or health service shall comply with any uncompensated care obligations required pursuant to the Act in a previous CON.

4400.3 The State Health Planning and Development Agency (SHPDA) may require each health care facility or health service subject to an uncompensated care obligation through a CON to submit data to verify compliance with the uncompensated care obligation.

4400.4 Each health care facility or health service subject to an uncompensated care obligation shall provide uncompensated care at the annual compliance level required by § 4400.2, for each fiscal year, or any part thereof, in which it is subject to the uncompensated care obligation.

4400.5 Each health care facility or health service that has an uncompensated care obligation shall make uncompensated care available to the extent of that

obligation to all eligible persons, without discrimination on the grounds of race, color, creed, national origin, sex, age, marital status, personal appearance, sexual orientation, family responsibilities, matriculation, political affiliation, physical handicap, source of income, or any other grounds unrelated to an individual's need for the service or the availability of the needed service.

4401 RESERVED

4402 CERTIFICATE OF NEED HOLDER PARTICIPATION IN THIRD PARTY PAYER PROGRAMS

4402.1 Each CON holder may make arrangements, if eligible to do so, for reimbursement for services from:

- (a) Those principal District and state third party payers that provide reimbursement for services; and
- (b) Federal governmental third-party programs, including Medicare and Medicaid.

4402.2 Each CON holder shall take all actions necessary to ensure that admission to and receipt of its services are available to beneficiaries of the governmental programs specified in § 4402.1, without discrimination or preference because they are beneficiaries of those programs.

4403 PROHIBITION OF EXCLUSIONARY ADMISSIONS POLICIES

4403.1 A CON holder shall be out of compliance with § 4400.4, if it uses an admissions practice that has the effect of excluding persons who are eligible for uncompensated care under § 4406.

4403.2 Prohibited admissions practices include the following:

- (a) Limiting admission to patients who are referred by physicians with staff privileges at the CON holder's facility (or facilities);
- (b) Maintaining an operational structure that includes few or no physicians with staff privileges who will treat persons who are eligible for uncompensated care; or
- (c) Requiring advance deposits (preadmission or pre-service deposits) from persons who qualify or appear to qualify for uncompensated care before admitting or serving these persons.

4403.3 A CON holder may have in effect a policy or practice described in § 4403.2(a) and still comply with this chapter if the CON holder makes alternative

arrangements to treat those persons who would otherwise be unable to gain admission to, or obtain services available from, the CON holder. Alternative arrangements may include the following:

- (a) Authorizing the individual's physician, if licensed and otherwise qualified, to treat the patient at the facility even though the physician does not have staff privileges at the facility;
- (b) Obtaining the voluntary agreement of physicians with staff privileges at the facility to accept referrals regularly of patients who do not have a physician (e.g. rotating referrals to the physicians with staff privileges);
- (c) Requiring acceptance of referrals of patients who do not have a physician as a condition of obtaining or renewing staff privileges;
- (d) Establishing a hospital-based primary care clinic through which patients needing hospitalization may be admitted; or
- (e) Hiring or contracting with qualified physicians to treat patients who do not have private physicians.

4403.4 A CON holder need not require all its staff physicians to accept Medicaid or Medicare patients to remedy a violation of § 4403.2(b). If the Department of Health, Medical Assistance Administration, determines that a CON holder or CON applicant is out of compliance with Medicaid or Medicare obligations, the CON applicant or CON holder shall be deemed out of compliance with admissions and service requirements until the CON applicant or CON holder takes steps to ensure that Medicaid and Medicare program beneficiaries have full access to all of the CON applicant's or CON holder's available services.

4403.5 A CON holder that engages in a practice prohibited by § 4403.2(c) is not required to forego the use of a deposit policy in all situations. The CON holder can remedy this violation by making alternative arrangements to ensure that persons who probably can pay for services are not denied them simply because they do not have the available cash at the time services are requested. A CON holder shall not deny admission or a service to a person who probably can pay because of the person's inability to pay a deposit at the time the person requests admission or a service.

4404 UNCOMPENSATED CARE COMPLIANCE REQUIREMENTS

4404.1 Each CON holder shall provide uncompensated care pursuant to § 4400.2 to eligible persons. The uncompensated care to be provided shall be based upon these rules or contractual obligations between the health care provider and the District of Columbia Government, whichever standard provides the higher dollar value.

- 4404.2 If, during any fiscal year, a CON holder fails to meet its annual uncompensated care obligation, the CON holder shall, during a subsequent fiscal year, provide uncompensated care in a dollar value sufficient to remediate that deficit, pursuant to a compliance plan under § 4413 approved by the SHPDA. The compliance plan shall include the following:
- (a) The conditions or circumstances that caused or contributed to the deficit;
 - (b) Specific actions the CON holder plans to take to remediate the deficit;
 - (c) Specific actions the CON holder plans to take to prevent further deficits;
 - (d) The name of a staff person who will be responsible for administering the compliance plan; and
 - (e) The dates on which the compliance plan will begin and is expected to be completed.
- 4404.3 A deficit incurred during any fiscal year shall be made up within not more than three (3) fiscal years after the end of the fiscal year during which the deficit occurred.
- 4404.4 A CON holder shall begin to make up a deficit during the fiscal year immediately following the fiscal year during which it incurred the deficit.
- 4404.5 The SHPDA shall complete its review of the compliance plan within forty-five (45) days of receipt from the CON holder. The compliance plan shall expire after the CON holder remedies the deficit for which it submitted the compliance plan.
- 4404.6 The Director may extend the period of time within which a CON holder may make up a deficit.
- 4404.7 The amount of an uncompensated care deficit for any fiscal year shall be the difference between a CON holder's annual compliance level for that fiscal year and the amount of uncompensated care provided during that fiscal year.
- 4404.8 If a CON holder provides uncompensated care during a fiscal year in an amount exceeding its annual compliance level, the CON holder may request that the Director apply the excess amount as a credit towards an existing deficit or its annual compliance level for any subsequent fiscal year. To be eligible for a credit, the excess dollar value above the annual compliance level must have been provided pursuant to the requirements of this chapter.

4405**NOTICE OF AVAILABILITY OF UNCOMPENSATED CARE**

4405.1 Each CON holder shall publish, in a newspaper of general circulation within the District of Columbia, and submit to the Director before the beginning of the CON holder's fiscal year, a notice of its uncompensated care obligation. The notice shall include:

- (a) The dollar value of uncompensated care that the CON holder intends to make available during the fiscal year or a statement that the CON holder will provide uncompensated care to all persons unable to pay for treatment who request uncompensated care;
- (b) An explanation of the difference between the amount of uncompensated care the CON holder proposes to make available and the annual compliance level for the CON holder, if any; and
- (c) A statement whether the CON holder has satisfied all outstanding uncompensated care obligations from previous reporting periods, or a statement indicating that it will, during a specified period, satisfy any outstanding obligations.

4405.2 The CON holder shall post the following notice:

"Under District of Columbia law, this health care provider must make its services available to all people in the community. This health care provider is not allowed to discriminate against a person because of race, color, religion, national origin, sex, age, marital status, personal appearance, sexual orientation, family responsibilities, matriculation, political affiliation, physical handicap, source of income, or place of residence or business, or because a person is covered by a program such as Medicare or Medicaid.

"This health care provider is also required to provide a reasonable volume of services without charge or at a reduced charge to persons unable to pay. Ask the staff if you are eligible to receive services either without charge or at a reduced charge. If you believe that you have been denied services or consideration for treatment without charge or at a reduced charge without a good reason, contact the Admissions or Business Office of this health care provider, and call the State Health Planning and Development Agency through the Citywide Call Center at 202-727-1000.

"If you want to file a complaint, forms are available from the State Health Planning and Development Agency."

4405.3 The notice required by § 4405.2 shall also include the CON holder's eligibility criteria for uncompensated care.

4405.4 The CON holder shall post the notice required by § 4405.2 in plain view in areas of the CON holder's facility or service that are easily accessible to the public. Those areas shall include the admissions areas, the business office, and the emergency room.

4405.5 The notice required by § 4405.2 shall be printed in the following languages:

- (a) English;
- (b) Spanish; and
- (c) Any other language that is the usual language of households of ten percent (10%) or more of the population of the District of Columbia, according to the most recent figures published by the Bureau of Census.

4405.6 Each CON holder shall communicate the contents of the posted notice to any person who the CON holder has reason to believe cannot read the notice.

4405.7 During any period of a fiscal year when uncompensated care is available in the CON holder's facility or service, the CON holder shall provide written notice of the availability of the services to each person who seeks services from the CON holder, whether on his or her own behalf or on behalf of another. The written notice of availability shall include the following:

- (a) The information set out in the notice in § 4405.2.
- (b) The location in the CON holder's facility or service where any person seeking uncompensated care may request it; and
- (c) A statement that the CON holder is required to make a written determination whether the person will receive uncompensated care; and
- (d) The date by, or period within which, the determination will be made.

4405.8 Each CON holder shall provide the written notice required by § 4405.7 before providing services, except where the emergency nature of the services makes prior notice impractical. In emergency situations, the CON holder shall provide the written notice to the patient as soon as practical, or to the next of kin. The CON holder shall give the notice not later than when presenting the first bill for services.

4406 UNCOMPENSATED CARE ELIGIBILITY CRITERIA

4406.1 A person is eligible to receive uncompensated care if the person is unable to pay for health services and satisfies the following additional requirements:

- (a) Is not covered, or receives services that are not covered, under a third-party insurer or governmental program;
- (b) Has an annual individual or family income that is not greater than two hundred percent (200%) of the federal poverty level; and
- (c) Requests services.

4406.2 Financial eligibility for uncompensated care shall be calculated by either of the following methods:

- (a) Multiplying by four (4) the person's individual or family income, as applicable, for the three (3) months preceding the request for uncompensated care; or
- (b) Using the person's or family's actual income, as applicable, for the twelve (12) months preceding the request for uncompensated care.

4406.3 For purpose of determining income eligibility for uncompensated care pursuant to § 4406.1(b), revisions to the federal poverty level used to calculate eligibility shall be effective sixty (60) days after the date of publication in the *Federal Register*.

4407 RESERVED

4408 WRITTEN DETERMINATION OF ELIGIBILITY FOR UNCOMPENSATED CARE

4408.1 Each CON holder shall give written notice of its determination of eligibility for uncompensated care in response to each request for uncompensated care to the person requesting care. The CON holder shall give notice in person at the time uncompensated care is requested or by regular mail to the address the person requesting services provided. If the person requesting care has not provided an address and is not available to receive notice in person, the CON holder may post at the facility, in a conspicuous place such as the admissions office or the emergency services department, a notice that the person's eligibility status is available in the administrative office within that facility.

4408.2 Each CON holder shall communicate the contents of the written determination to any person requesting uncompensated care that the CON holder has reason to believe cannot read the determination.

4408.3 Each determination of eligibility for uncompensated care shall include the following statements:

- (a) That the CON holder will, will with conditions, or will not provide uncompensated care;

- (b) That there will be no charge for uncompensated care;
- (c) The date on which the person requested care;
- (d) The date on which the CON holder made the determination;
- (e) The annual individual or family income, as applicable, and family size of the person who requested uncompensated care;
- (f) The date on which services were, or will be, provided; and
- (g) The reason for denial, if applicable.

4408.4 As a condition of providing uncompensated care, a CON holder may:

- (a) Require the person requesting uncompensated care to furnish any information that is reasonably necessary to substantiate eligibility; and
- (b) Require each person requesting uncompensated care to apply for any benefits under third party insurer or governmental programs to which the person requesting uncompensated care is, or could be, entitled upon application.

4408.5 A conditional eligibility determination shall state the conditions that the person requesting uncompensated care must satisfy to be eligible.

4408.6 CON holders shall make eligibility determinations as follows:

- (a) Each hospital shall make an eligibility determination for uncompensated care within five (5) business days of a request for an outpatient service or before discharge for an inpatient service;
- (b) Each ambulatory surgical facility shall make an eligibility determination for uncompensated care within five (5) business days of a request for an outpatient service; and
- (c) Any other CON holder shall make a determination of eligibility for uncompensated care within ten (10) business days following the date of admission or delivery of services.

4409 RESERVED

4410 UNCOMPENSATED CARE REPORTING REQUIREMENTS

4410.1 Each CON holder shall submit an annual report to the SHPDA on uncompensated care. The report shall be on a schedule prescribed by the SHPDA. The report shall

be submitted within one hundred and twenty (120) days after the close of the CON holder's fiscal year. The report shall include:

- (a) The dollar value of uncompensated care that the CON holder was required to provide;
- (b) The dollar value of uncompensated care the CON holder actually provided, with the dollar value of charity care and bad debt reported separately;
- (c) A copy of the CON holder's audited financial statement for that fiscal year;
- (d) Other documentation SHPDA may require to determine if a CON holder has met its annual compliance level for the period covered by the report;
- (e) The dollar value of services and care provided to District residents;
- (f) A copy of the notice required by § 4405.1, including the date the notice was published and the name of the newspaper that printed the notice;
- (g) If the CON holder failed to provide the required annual level of uncompensated care, the reason and any documentation that supports its reason for failing to meet the annual compliance level; and
- (h) Any other documentation the Director may request.

4410.2 The Director may require a CON holder to submit the report required by § 4410.1 more frequently when:

- (a) The Director determines that during the preceding fiscal year the CON holder did not provide uncompensated care at its required annual compliance level; or
- (b) The Director notifies the CON holder, in writing, that additional reports are needed for proper administration of the CON program.

4410.3 If the Director requests additional reports pursuant to § 4410.2, the CON holder shall submit the report within ninety (90) days after receiving the request or within ninety (90) days after the close of the fiscal year, whichever is later. The Director may, for good cause shown, extend the time within which the CON holder must submit the report.

4410.4 Not later than ten (10) days after being served with a summons or complaint regarding uncompensated care or any other activity relating to the CON, each CON holder shall notify the Director of any legal action brought against it that alleges that it has failed to comply with the requirements of this chapter.

4411 UNCOMPENSATED CARE RECORDS MAINTENANCE REQUIREMENTS

4411.1 Each CON holder shall maintain and provide to the Director, upon request, any records necessary to document the CON holder's compliance with the requirements of this chapter. Each CON holder shall make available for public inspection the records it maintains to document its compliance. Patient identifying information shall be removed from records provided for public inspection.

4411.2 The CON holder shall maintain uncompensated care records, including the following:

- (a) Any documents from which the information required to be reported under § 4410 was obtained;
- (b) Documents that clearly segregate uncompensated care from other accounts;
- (c) Copies of written determinations of eligibility under § 4408; and
- (d) Documentation that verifies compliance with the requirements of this chapter during any fiscal year, including documents from which information required to be reported under § 4410.1 was obtained.

4411.3 Each CON holder shall retain records to document its compliance with this chapter for five (5) years from the date of the last entry for a particular fiscal year. The Director may require a CON holder to maintain the records for a longer period.

4412 INVESTIGATION AND CERTIFICATION OF COMPLIANCE

4412.1 Any person may file a complaint with the Director that a CON holder is not complying with the requirements of this chapter.

4412.2 Each complaint shall include the following information:

- (a) The name and address of the complainant;
- (b) The name and address of the CON holder;
- (c) The date or approximate date on which the event or incident being complained of occurred; and
- (d) A statement describing the event or incident that the complainant believes violates the requirements of this chapter.

4412.3 The filing date of a complaint shall be the date of receipt by the SHPDA.

- 4412.4 The Director shall provide a copy of the complaint to the CON holder named in the complaint within ten (10) business days after receiving the complaint.
- 4412.5 The Director shall initiate an investigation of each complaint filed pursuant to the provisions of this section within thirty (30) business days of its receipt.
- 4412.6 The CON holder shall provide the Director with documents, records, or other requested information that may assist in investigating the complaint.
- 4412.7 A CON holder shall be out of compliance with its uncompensated care obligations if it fails to provide documentation the Director requests to determine the CON holder's compliance with this chapter.
- 4412.8 The Director shall determine the merit of a complaint based on:
- (a) Information contained in the complaint;
 - (b) Documents the CON holder provides; and
 - (c) Other credible information the Director receives.
- 4412.9 If the Director determines that a complaint is not substantiated, the Director shall dismiss the complaint.
- 4412.10 The Director shall make periodic reviews of the uncompensated care requirements and activities of each CON holder to determine whether a CON holder is complying with its obligations.
- 4412.11 The Director shall conduct audits to determine each CON holder's compliance with its uncompensated care obligation according to standard audit procedures.
- 4412.12 After completing the audit the Director may certify that a CON holder has substantially complied with its uncompensated care obligation for a specific fiscal year or years. The certification shall confirm that the CON holder has provided the uncompensated care stated for the period covered by the certification.
- 4412.13 The Director shall base each certification of substantial compliance on the amount of uncompensated care properly claimed by the CON holder, using procedures and reviewing individual account data the Director determines to be sufficient to establish that the CON holder has substantially complied with its uncompensated care obligation for the period covered by the certification.
- 4412.14 The Director may certify substantial compliance when he or she determines that, for the period covered by the certification, the CON holder provided uncompensated care to eligible persons who had equal opportunity to apply for

uncompensated care.

4412.15 To determine whether a CON holder has substantially complied with its obligations, the SHPDA shall consider each of the following in descending order of importance:

- (a) Whether the CON holder took corrective action prescribed pursuant to § 4413;
- (b) Whether the CON holder's noncompliance with its uncompensated care obligation may be remedied by corrective action under § 4413; and
- (c) Whether the CON holder had procedures in place that complied with the applicable notice, eligibility, and record keeping requirements of §§ 4405, 4406, 4408, 4410, and 4411, and systematically and correctly followed the procedures.

4412.16 The Director shall determine and certify the amount of creditable service required by each CON holder for the three (3) fiscal years ending prior to the effective date of these rules. The Director shall base the determination on information necessary to establish the CON holder's substantial compliance with its uncompensated care obligation during the period being reviewed.

4412.17 To determine creditable service during the three (3) fiscal years ending prior to the effective date of these rules, each CON holder shall submit to the Director for each fiscal year the following:

- (a) The number of persons to whom it provided care without charge or below its normal and customary charge;
- (b) The total dollar amount of uncompensated care it provided in each fiscal year and the method used to determine that dollar amount; and
- (c) A description of the eligibility criteria it used for providing uncompensated care.

4413 UNCOMPENSATED CARE ENFORCEMENT

4413.1 If the Director finds, based on an investigation, review, or audit under § 4412, that a CON holder has not complied with the requirements of this chapter, the Director may take any action authorized by law to secure compliance, including:

- (a) Voluntary agreement;
- (b) Judicial enforcement of the obligations under this chapter; and

(c) Denial or withdrawal of a CON.

4413.2 Each CON holder that has denied uncompensated care to any person because it failed to comply with its uncompensated care obligation shall be out of compliance until it takes the actions necessary to remedy fully the noncompliance, including;

(a) Providing uncompensated care to applicants improperly denied;

(b) Repaying amounts improperly collected from persons eligible to receive uncompensated care; and

(c) Other corrective action the Director may prescribe.

4413.3 The Director may disallow all of the uncompensated care claimed in a fiscal year if the Director finds that a CON holder was in substantial noncompliance with its uncompensated care obligation because it failed to do any of the following:

(a) Have a system for providing notices to eligible persons as required by § 4405;

(b) Comply with the applicable reporting requirements of § 4410;

(c) Have a system for maintaining records of uncompensated care provided;

(d) Take corrective action pursuant to § 4413.2;

(e) Comply with the applicable eligibility standards in § 4406; or

(f) Comply with the written determination procedures in § 4408.

4413.4 If the Director determines, based on investigation, audit, or review under § 4412, that a CON holder has limited its services in violation of its uncompensated care obligation, the Director may require the CON holder to establish a compliance plan to ensure that the CON holder's services are available according to the requirements of this chapter.

4413.5 In the absence of a finding of noncompliance in any fiscal year, the Director may disallow uncompensated care claimed by a CON holder in the fiscal year to the extent that the services are not documented as uncompensated care according to this chapter.

4412 RESERVED

4499**DEFINITIONS**

4499.1 The provisions of § 4099 of Chapter 40 of this title and the definitions set forth in that section shall apply to this chapter.

4499.2 When used in this chapter, the following terms and phrases shall have the meaning ascribed below:

Act - the Health Services Planning Program Re-establishment Act of 1996, effective April 9, 1997 (D.C. Law 11-191; D.C. Official Code § 44-401 et seq.).

Certificate of Need or CON - authorization for a health care facility or health service to develop a new institutional health service, purchase major medical equipment, or obligate a capital expenditure to obtain an asset worth more than two million five hundred thousand dollars (\$2,500,000).

Certificate of Need applicant or CON applicant - a person who applies for a CON.

Certificate of Need holder or CON holder - a person who has applied for and received a Certificate of Need pursuant to this chapter. For the purpose of this chapter, a person continues to be a CON holder after the completion of the project for which the CON was obtained.

Compliance plan - the means by which a CON holder that violates this chapter or is out of compliance with its uncompensated care obligations proposes to remedy the violations or other noncompliance.

Director - Director of the District of Columbia State Health Planning and Development Agency, Department of Health.

Health care facility- a private general hospital, psychiatric hospital, other specialty hospital, rehabilitation facility, skilled nursing facility, intermediate care facility, ambulatory care center or clinic, ambulatory surgical facility, kidney disease treatment center, freestanding hemodialysis facility, diagnostic health care facility, home health agency, hospice, or other comparable health care facility that has an annual operating budget of at least \$500,000. This term shall not include Christian Science sanitariums operated, listed, and certified by the First Church of Christ Scientist, Boston, Massachusetts; the private office facilities of a health professional or group of health professionals, where the health professional or group of health professionals provides conventional office services limited to medical consultation, general non-invasive examination, and minor treatment, or a health care facility licensed or to be licensed as a community residence facility, or an Assisted Living Residence as defined by § 102.01(4) of the

Assisted Living Residence Regulatory Act of 2000, effective June 24,2000 (D.C. Law 13-127; 44-102.01(4)).

Health service - any medical or clinical related service, including services that are diagnostic, curative, or rehabilitative, as well as those related to alcohol abuse, inpatient mental health services, home health care, hospice care, medically supervised day care, and renal dialysis. This term shall not include those services provided by physicians, dentists, HMOs, and other individual providers in individual or group practice.

Request for uncompensated care - any indication by or on behalf of an individual seeking health care from a CON holder of the individual's inability to pay for the services that is made at any time, including following institution of a collection action against the individual.

SHPDA - State Health Planning and Development Agency, Department of Health.

CHAPTER 45 DATA REPORTING

4500 REPORTS

4500.1 Pursuant to D.C. Official Code §44-405(b), a HCF or a person holding a CON under the Act shall submit to SHPDA periodic data reports related to the development of proposals subject to CON review.

4500.2 The requirements of this chapter may be supplemented, from time to time, with requirements for additional data when the data is reasonably necessary for SHPDA to carry out its mission under the Act. When the Director requires additional data from an HCF, the Director shall give written notice of the requirement not less than sixty (60) days before implementing the requirement. The notice required by this section shall include the basis for the requirements.

4501 DATA REPORTING

4501.1 An HCF subject to the requirements of Subsection 4500.1 shall submit to SHPDA, or to a data processing agent specified by SHPDA, the data described in this chapter, or other similar data that SHPDA may request.

4501.2 A person or entity required to file a report under this chapter shall report the data in the form and format and according to the schedule SHPDA designates. The data shall be submitted on a form prescribed by SHPDA.

4501.3 An annual report required by this chapter shall be submitted not later than ninety (90) days after the end of the report period.

4501.4 Data due less often than annually shall be submitted no later than sixty (60) days

following the end of the report period.

4502 REPORT CATEGORIES

4502.1 A report submitted pursuant to Sections 4506 and 4507 of this chapter shall use the following age categories:

- (a) Eighteen (18) years of age and younger; and
- (b) Over (18) years.

4502.2 A report that requires listing a patient's residence under Sections 4506, 4507, and 4511 of this chapter shall use the following categories:

- (a) District of Columbia;
- (b) Maryland--Calvert County;
- (c) Maryland--Charles County;
- (d) Maryland--Montgomery County;
- (e) Maryland--Prince George's County;
- (f) Maryland--St. Mary's County;
- (g) Maryland--other counties;
- (h) Virginia--Alexandria City;
- (i) Virginia--Arlington County;
- (j) Virginia--Fairfax County (including Fairfax City and Falls Church);
- (k) Virginia--Loudon County;
- (l) Virginia--Prince William County (including Manassas and Manassas Park);
- (m) Virginia--other counties;
- (n) Other states and foreign countries; and
- (o) Residence unknown.

4503 FINANCIAL REPORTS

4503.1 An HCF or health service shall submit to SHPDA, not later than one-hundred and twenty (120) days following the end of the fiscal year being reported upon, a copy of its audited financial report.

4503.2 The audited financial report and supplemental data supplied with the report shall include the following information, as applicable:

- (a) Balance sheet;
- (b) Income statement;
- (c) Cash flow schedule;
- (d) Costs statement, including payroll costs, inpatient care costs, outpatient care costs, capital costs, and operating costs;
- (e) Per Diem rates for inpatient room types;
- (f) Rate structure;
- (g) Average cost per patient day;
- (h) Average cost and average charge per outpatient visit;
- (i) Average cost and average charge per emergency room visit; and
- (j) Revenues, including specification of Medicaid revenue, Medicare revenue, other third-party revenue, and self-pay revenue.

4504 ANNUAL REPORTS

4504.1 A hospital of any type, unless specifically exempted by SHPDA, shall provide annually, the data required in Subsection 4504.2 for each of the following services:

- (a) Total medical-surgical services (including intensive care beds, and cardiac care services);
- (b) Intensive care service;
- (c) Coronary care service;
- (d) Obstetrics service;

- (e) Obstetrics-gynecology swing service;
- (f) Nursery service;
- (g) Intermediate neonatal and neonatal intensive care services;
- (h) Pediatric service;
- (i) Psychiatric service;
- (j) Rehabilitation service;
- (k) Alcoholism-chemical dependency service;
- (l) Diagnostic imaging;
- (m) Emergency service;
- (n) Radiation therapy; and
- (o) Any other service that SHPDA specifies after giving notice to the hospital at least thirty (30) days before the beginning of the period for which the data is required.

4504.2 A hospital subject to § 4504.1 shall submit a report including the following information for each service specified in that subsection:

- (a) The number of patients admitted during the reporting period for the purpose of receiving inpatient nursing care; in the nursery service, the number of admissions refers to newborn infants admitted to the hospital following birth and infants admitted following transfer from home or another hospital; in the intensive and coronary care units, the number of admissions include only those patients directly admitted to the units; patients initially admitted to the medical-surgical service and later transferred to intensive care shall be reported as intra-hospital transfers to those units;
- (b) The number of deliveries, the complete expulsion or extraction from its mother of a product of conception, regardless of the duration of pregnancy (excludes induced abortions); the number of deliveries includes live births and fetal deaths; multiple births shall be counted as one (1) delivery;
- (c) The number of emergency room registrants, including the sum of visits to the emergency room and psychiatric emergency services that result in the acceptance of the patient for the purpose of receiving inpatient nursing care within the hospital;

- (d) The number of deaths that occur before the complete expulsion or extraction from its mother of a product of conception; death is indicated by the fact that after separation from the mother, a fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles (excludes induced abortions);
- (e) The number of patients receiving surgical procedures that are performed exclusively on an outpatient basis;
- (f) The number of live births, which is the complete expulsion or extraction from its mother of a product of conception (regardless of the duration of pregnancy) that, after separation from its mother, breathes or shows any other evidence of life (such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles) whether or not the umbilical cord has been cut or the placenta is attached;
- (g) The number of bassinets or cribs regularly maintained for use by infants as of the last day of the reporting period;
- (h) The number of beds regularly maintained for use by inpatients as of the last day of the reporting period;
- (i) The number of patients who registered to receive care in an organized outpatient department;
- (j) The total number of patient days of care rendered during the reporting period (*i.e.*, the cumulative sum of the number of occupied beds in a particular service on each day of the reporting period); and
- (k) Other data that SHPDA may require.

4505 ANNUAL DISCHARGE DATA REPORTS

4505.1 Each hospital, unless specifically exempted by SHPDA, shall provide annually, in a form, format, and medium designated by SHPDA, a hospital discharge data set including the following information for each patient:

- (a) Age;
- (b) Sex;
- (c) Race;
- (d) Major hospital service;

- (e) Disposition;
- (f) Patient residence;
- (g) Admission date;
- (h) Discharge date;
- (i) Expected source of payment;
- (j) Principal diagnosis and other diagnoses;
- (k) Principal procedure and other procedures;
- (l) Hospital identification;
- (m) Patient sequence number (assigned in a way unrelated to the medical record number);
- (n) Birth weight in grams (neonates only);
- (o) Financial data;
- (p) Ward; and
- (q) Other data that SHPDA may require.

4505.2 Hospital discharge data shall be submitted not later than one-hundred and twenty (120) days following the end of the year being reported upon.

4506 HEART SURGERY REPORTS

4506.1 Each hospital, unless specifically exempted by SHPDA, shall report annually the number of open heart surgery operations performed by patient age and patient residence categories for each of the following:

- (a) Congenital heart disease;
- (b) Valvular heart disease;
- (c) Coronary heart disease; and
- (d) Other.

4506.2 Each hospital, unless specifically exempted by SHPDA, shall report annually the

number of closed heart surgery operations and the number of all other cardiac operations not reported under Subsection 4506.1, reported by the patient age and patient residence categories specified in Section 4502, performed for the following:

- (a) Congenital heart disease;
- (b) Valvular heart disease; and
- (c) Other.

4506.3 Each hospital, unless specifically exempted by SHPDA, shall report annually the cardiac surgery operative mortality (the number of deaths within thirty (30) days) reported by the patient age categories specified in Section 4502, for the following:

- (a) Open heart surgery - coronary bypass;
- (b) Open heart surgery - all others;
- (c) Closed heart surgery; and
- (d) Other cardiac surgery.

4506.4 For the purposes of this section, the term “open heart surgery” includes an operation that uses a mechanical pump to temporarily perform the function of circulation during surgery.

4506.5 For the purposes of this section, the term “closed heart surgery” includes an operation that does not require the use of a mechanical pump during surgery. Closed heart surgery shall include the following:

- (a) Valve commissurotomy;
- (b) Thoracic aneurysm repair or transection;
- (c) Systemic pulmonary shunt;
- (d) Ligation/division of patent ductus arteriosus;
- (e) Resection of coarctation of aorta;
- (f) Pulmonary artery banding; and
- (g) Valvulotomy.

4506.6 For the purposes of this section, pacemaker implantations and implants of

pulsation balloons are excluded from the category of operations defined as “closed heart surgery.”

4507

CARDIAC CATHETERIZATION REPORTS

4507.1

Each hospital, unless specifically exempted by SHPDA, shall report annually the number of procedures performed in the cardiac catheterization laboratory in the categories specified below by the patient age and patient residence categories specified in Section 4502 (the procedure includes all diagnostic studies, angiographic and physiologic, performed on a patient during one (1) session in the laboratory):

- (a) Right heart catheterizations (with and without angiography);
- (b) Left heart catheterizations without coronary angiography;
- (c) Left heart catheterizations with coronary angiography;
- (d) Combined right and left heart catheterizations without angiography;
- (e) Combined right and left heart catheterizations with angiography (other than coronary angiography);
- (f) Combined right and left heart catheterizations with coronary angiography;
- (g) Permanent pacemaker implantation;
- (h) Other cardiac procedures (includes temporary pacemakers);
- (i) Electrophysiological studies (*e.g.*, HIS Bundle);
- (j) Percutaneous transluminal coronary angioplasty (PTCA);
- (k) Streptokinase thrombolysis; and
- (l) Other non-cardiac angiographic procedures.

4507.2

Each hospital, unless specifically exempted by SHPDA, shall report annually the number of cardiac catheterization patients in the following categories by each patient age and patient residence category specified in Section 4502:

- (a) Number of cardiac patients studied;
- (b) Number of non-cardiac patients studied;
- (c) Number of patients studied with pre-catheterization diagnosis of the

following:

- (1) Coronary artery disease;
- (2) Coronary artery and valvular or congenital disease;
- (3) Valvular or congenital disease only; and
- (4) Other diseases.

4507.3 Each hospital, unless specifically exempted by SHPDA, shall report annually the cardiac catheterization mortality (the number of deaths when mortality occurs during or immediately following surgery), reported by the patient age and patient residence categories specified in Section 4502.

4508 EMERGENCY ROOM REPORTS

4508.1 Each hospital, unless specifically exempted by SHPDA, shall report annually, on the basis of a one (1) week sample survey, the number of emergency room encounters that were judged not to require emergency service.

4508.2 SHPDA shall notify a hospital at least three (3) months in advance of the selected week for the survey required in Subsection 4508.1.

4508.3 Each hospital, unless specifically exempted by SHPDA, shall report quarterly the data listed below:

- (a) Average daily hours of operation;
- (b) Average daily hours on diversion;
- (c) Average daily hours closed;
- (d) Average daily number of patients; and
- (e) Severity quotient;

4509 REPORTS OF OTHER FACILITIES

4509.1 Each SNF and each ICF shall provide the following data annually:

- (a) The number of operating (staffed and otherwise held ready for occupancy) beds, by bed category (*i.e.*, SNF and ICF);
- (b) The number of patient days by bed category;

- (c) The jurisdiction of residence of patients at the time of admission, by bed category (using the jurisdiction categories specified in Section 4502);
- (d) The number of admissions by bed category;
- (e) The number of discharges by bed category;
- (f) The average length of stay by bed category;
- (g) Payment source by days of care by bed category; and
- (h) Long-term acute care.

4509.2 Each renal dialysis facility shall report annually, by jurisdiction of patient residence (using the categories as specified in Section 4502), the number of patients regularly receiving each type of service the facility offers, the number of treatments given by type, and the facility's hours of operation.

4509.3 Each home health agency and each home care hospice shall report annually the number of patients serviced, and the number of visits provided, by type and major payment source (Medicaid, Medicare, other third party, and self-pay) and any other information SHPDA may request.

4509.4 Each ambulatory surgical facility, neighborhood health center, drug treatment center, alcohol treatment clinic, and other freestanding medical facility subject to CON requirements, shall report annually the number of patients serviced, the number of patient encounters, and, if applicable, the number of enrollees by major payment source.

4509.5 Each HMO shall annually report the number of enrollees by the following categories:

- (a) Jurisdiction of residence as specified Section 4502;
- (b) The number of ambulatory visits;
- (c) The number of hospital admissions (by hospital); and
- (d) The number of inpatient days of care (by hospital and service).

4599 DEFINITIONS

4599.1 The provisions of § 4099 of Chapter 40 of this title, and the definitions set forth in that section shall apply to this chapter.

Chapter 46 (Revised Special Certificate Of Need Procedures, Considerations And Criteria

For Review Of Magnetic Resonance Imaging (MRI) Scanners), is repealed in its entirety.