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HOUSE BILL NO. 2277

Offered January 10, 2007

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A BILL to amend and reenact §§ 32.1-102.1, 32.1-102.3, 32.1-102.6, 32.1-102.12, and 32.1-122.05 of the Code of Virginia, relating to certificates of public need.

Patron—Purkey

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-102.1, 32.1-102.3, 32.1-102.6, 32.1-102.12, and 32.1-122.05 of the Code of Virginia are amended and reenacted as follows:

§ 32.1-102.1. Definitions.

As used in this article, unless the context indicates otherwise:

"Certificate" means a certificate of public need for a project required by this article.

"Clinical health service" means a single diagnostic, therapeutic, rehabilitative, preventive or palliative procedure or a series of such procedures that may be separately identified for billing and accounting purposes.

"Health planning region" means a contiguous geographical area of the Commonwealth with a population base of at least 500,000 persons which is characterized by the availability of multiple levels of medical care services, reasonable travel time for tertiary care, and congruence with planning districts.

"Medical care facility," as used in this title, means any institution, place, building or agency, whether or not licensed or required to be licensed by the Board or the State Mental Health, Mental Retardation and Substance Abuse Services Board, whether operated for profit or nonprofit and whether privately owned or privately operated or owned or operated by a local governmental unit, (i) by or in which health services are furnished, conducted, operated or offered for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition, whether medical or surgical, of two or more nonrelated mentally or physically sick or injured persons, or for the care of two or more nonrelated persons requiring or receiving medical, surgical or nursing attention or services as acute, chronic, convalescent, aged, physically disabled or crippled or (ii) which is the recipient of reimbursements from third-party health insurance programs or prepaid medical service plans. For purposes of this article, only the following medical care facilities shall be subject to review:

1. General hospitals.

2. Sanitariums.

3. Nursing homes.

4. Intermediate care facilities, except those intermediate care facilities established for the mentally retarded that have no more than 12 beds and are in an area identified as in need of residential services for people with mental retardation in any plan of the Department of Mental Health, Mental Retardation and Substance Abuse Services.

5. Extended care facilities.

6. Mental hospitals.

7. Mental retardation facilities.

8. Psychiatric hospitals and intermediate care facilities established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts.

9. Specialized centers or clinics or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, radiation therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, or such other specialty services as may be designated by the Board by regulation.

10. Rehabilitation hospitals.

11. Any facility licensed as a hospital.

The term "medical care facility" shall not include any facility of (i) the Department of Mental Health, Mental Retardation and Substance Abuse Services; (ii) any nonhospital substance abuse residential treatment program operated by or contracted primarily for the use of a community services board under the Department of Mental Health, Mental Retardation and Substance Abuse Services' Comprehensive Plan; (iii) an intermediate care facility for the mentally retarded that has no more than 12 beds and is in an area identified as in need of residential services for people with mental retardation in any plan of the

Department of Mental Health, Mental Retardation and Substance Abuse Services; (iv) a physician's office, except that portion of a physician's office described above in subdivision 9 of the definition of "medical care facility"; or (v) the Woodrow Wilson Rehabilitation Center of the Department of Rehabilitative Services. "Medical care facility" shall also not include that portion of a physician's office dedicated to providing nuclear cardiac imaging.

"Project" means:

1. Establishment of a medical care facility;

2. An increase in the total number of beds or operating rooms in an existing medical care facility;

3. Relocation at the same site of 10 beds or 10 percent of the beds, whichever is less, from one existing physical facility to another in any two-year period; however, a hospital shall not be required to obtain a certificate for the use of 10 percent of its beds as nursing home beds as provided in § 32.1-132;

4. Introduction into an existing medical care facility of any new nursing home service, such as intermediate care facility services, extended care facility services, or skilled nursing facility services, regardless of the type of medical care facility in which those services are provided;

5. Introduction into an existing medical care facility of any new cardiac catheterization, computed tomographic (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), medical rehabilitation, neonatal special care, obstetrical, open heart surgery, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant service, radiation therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, substance abuse treatment, or such other specialty clinical services as may be designated by the Board by regulation, which the facility has never provided or has not provided in the previous 12 months;

6. Conversion of beds in an existing medical care facility to medical rehabilitation beds or psychiatric beds;

7. The addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, or other specialized service designated by the Board by regulation. Replacement of existing equipment shall not require a certificate of public need; or

8. Any capital expenditure of $5 million or more, not defined as reviewable in subdivisions 1 through 7 of this definition, by or in behalf of a medical care facility. However, capital expenditures between $1 and $5 million shall be registered with the Commissioner pursuant to regulations developed by the Board.

~~"Regional health planning agency" means the regional agency, including the regional health planning board, its staff and any component thereof, designated by the Virginia Health Planning Board to perform the health planning activities set forth in this chapter within a health planning region.~~

"State Medical Facilities Plan" means the planning document adopted by the Board of Health which shall include, but not be limited to, (i) methodologies for projecting need for medical care facility beds and services; (ii) statistical information on the availability of medical care facilities and services; and (iii) procedures, criteria and standards for review of applications for projects for medical care facilities and services.

"Virginia Health Planning Board" means the statewide health planning body established pursuant to § 32.1-122.02 which serves as the analytical and technical resource to the Secretary of Health and Human Resources in matters requiring health analysis and planning.

§ 32.1-102.3. Certificate required; criteria for determining need.

A. No person shall commence any project without first obtaining a certificate issued by the Commissioner. No certificate may be issued unless the Commissioner has determined that a public need for the project has been demonstrated. If it is determined that a public need exists for only a portion of a project, a certificate may be issued for that portion and any appeal may be limited to the part of the decision with which the appellant disagrees without affecting the remainder of the decision. Any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan; however, if the Commissioner finds, upon presentation of appropriate evidence, that the provisions of such plan are not relevant to a rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable, the Commissioner, consistent with such finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan.

B. In determining whether a public need for a project has been demonstrated, the Commissioner shall consider:

~~1. The recommendation and the reasons therefor of the appropriate health planning agency.~~

~~2~~*1*. The relationship of the project to the applicable health plans of the Board ~~and the health planning agency~~.

~~3~~*2*. The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.

~~4~~*3*. The need that the population served or to be served by the project has for the project, including, but not limited to, the needs of rural populations in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

~~5~~*4*. The extent to which the project will be accessible to all residents of the area proposed to be served and the effects on accessibility of any proposed relocation of an existing service or facility.

~~6~~*5*. The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health service area in which the project is proposed, in particular, the distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

~~7~~*6*. Less costly or more effective alternate methods of reasonably meeting identified health service needs.

~~8~~*7*. The immediate and long-term financial feasibility of the project.

~~9~~*8*. The relationship of the project to the existing health care system of the area in which the project is proposed; however, for projects proposed in rural areas, the relationship of the project to the existing health care services in the specific rural locality shall be considered.

~~10~~*9*. The availability of resources for the project.

~~11~~*10*. The organizational relationship of the project to necessary ancillary and support services.

~~12~~*11*. The relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.

~~13~~*12*. The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health service area in which the project is to be located.

~~14~~*13*. The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the Commissioner may grant a certificate for a project if the Commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organization or the beds or services to be provided are not available from providers which are not health maintenance organizations or from other health maintenance organizations in a reasonable and cost-effective manner.

~~15~~*14*. The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

~~16~~*15*. In the case of a construction project, the costs and benefits of the proposed construction.

~~17~~*16*. The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.

~~18~~*17*. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.

~~19~~*18*. In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed, including, in the case of rural localities, any distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

~~20~~*19*. The need and the availability in the health service area for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.

§ 32.1-102.6. Administrative procedures.

A. *At least 30 calendar days before any person is contractually obligated to acquire an existing medical care facility, the cost of which is $600,000 or more, that person shall notify the Commissioner and the appropriate health planning agency of the intent, the services to be offered in the facility, the bed capacity in the facility, and the projected impact that the cost of the acquisition will have upon the charges for services to be provided. If clinical services or beds are proposed to be added as a result of the acquisition, the Commissioner may require the proposed new owner to obtain a certificate prior to the acquisition.*

B. To obtain a certificate for a project, the applicant shall file a completed application for a certificate with the Department ~~and the appropriate health planning agency~~. In order to verify the date of the Department's ~~and the appropriate health planning agency's~~ receipt of the application, the applicant shall transmit the document by certified mail or a delivery service, return receipt requested, or shall deliver the document by hand, with signed receipt to be provided.

Within 10 calendar days of the date on which the document is received, the Department ~~and the appropriate health planning agency~~ shall determine whether the application is complete or not and the Department shall notify the applicant, if the application is not complete, of the information needed to complete the application.

~~At least 30 calendar days before any person is contractually obligated to acquire an existing medical care facility, the cost of which is $600,000 or more, that person shall notify the Commissioner and the appropriate health planning agency of the intent, the services to be offered in the facility, the bed capacity in the facility and the projected impact that the cost of the acquisition will have upon the charges for services to be provided. If clinical services or beds are proposed to be added as a result of the acquisition, the Commissioner may require the proposed new owner to obtain a certificate prior to the acquisition.~~

~~B. The appropriate health planning agency shall review each completed application for a certificate within 60 calendar days of the day which begins the appropriate batch review cycle as established by the Board by regulation pursuant to subdivision A 1 of § 32.1-102.2, such cycle not to exceed 190 days in duration. The health planning agency shall hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city. The health planning agency shall cause notice of the public hearing to be published in a newspaper of general circulation in the county or city where a project is proposed to be located at least nine calendar days prior to the public hearing. Prior to the public hearing, the health planning agency shall notify the local governing bodies in the planning district. The health planning agency shall consider the comments of such governing bodies and all other public comments in making its decision. Such comments shall be part of the record provided to the Department. In no case shall a health planning agency hold more than two meetings on any application, one of which shall be the public hearing conducted by the board of the health planning agency or a subcommittee of the board. The applicant shall be given the opportunity, prior to the vote by the board of the health planning agency or a committee of the agency, if acting for the board, on its recommendation, to respond to any comments made about the project by the health planning agency staff, any information in a staff report, or comments by those voting; however, such opportunity shall not increase the 60-calendar-day period designated herein for the health planning agency's review unless the applicant or applicants request a specific extension of the health planning agency's review period.~~

~~The health planning agency shall submit its recommendations on each application and its reasons therefor to the Department within 10 calendar days after the completion of its 60-calendar-day review or such other period in accordance with the applicant's request for extension.~~

~~If the health planning agency has not completed its review within the specified 60 calendar days or such other period in accordance with the applicant's request for extension and submitted its recommendations on the application and the reasons therefor within 10 calendar days after the completion of its review, the Department shall, on the eleventh calendar day after the expiration of the health planning agency's review period, proceed as though the health planning agency has recommended project approval without conditions or revision.~~

~~C. After commencement of any public hearing and before a decision is made there shall be no ex parte contacts concerning the subject certificate or its application between (i) any person acting on behalf of the applicant or holder of a certificate or any person opposed to the issuance or in favor of revocation of a certificate of public need and (ii) any person in the Department who has authority to make a determination respecting the issuance or revocation of a certificate of public need, unless the Department has provided advance notice to all parties referred to in (i) of the time and place of such proposed contact.~~

~~D~~*C.* The Department shall commence the review of each completed application upon the day ~~which~~ *that* begins the appropriate batch review cycle ~~and simultaneously with the review conducted by the health planning agency~~ *as established by regulations promulgated pursuant to § 32.1-102.2. Such review shall not exceed 120 calendar days.*

A determination *as to* whether a public need exists for a project shall be made by the Commissioner within ~~190~~ *120* calendar days of the day which begins the appropriate batch cycle.

The ~~190-calendar-day~~ *120-calendar-day* review period shall begin on the date upon which the application is determined to be complete within the batching process specified in subdivision A 1 of § 32.1-102.2.

If the application is not determined to be complete within 40 calendar days from submission, the application shall be refiled in the next batch for like projects.

D. The Department shall hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city. The Department shall cause notice of the public hearing to be published in a newspaper of general circulation in the county or city where a project is proposed to be located at least nine calendar days prior to the public hearing. Prior to the public hearing, the Department shall notify the local governing bodies in the planning district. The Department shall consider the comments of such governing bodies and all other public comments in making its decision. Such comments shall be part of the record. In no case shall the Department hold more than two meetings on any application.

E. After commencement of any public hearing and before any decision is made there shall be no ex

parte contact concerning the subject certificate or its application between (i) any person acting on behalf of the application or holder of a certificate or any person opposed to the issuance or in favor of revocation of a certificate of public need and (ii) any person in the Department who has authority to make a determination respecting the issuance or revocation of a certificate of public need, unless the Department has provided advance notice to all parties referred to in clause (i) of the time and place of the proposed contact.

F. The Commissioner shall make determinations in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.) except for those parts of the determination process for which timelines and specifications are delineated in subsection ~~E~~ *G* ~~of this section~~. Further, if an informal fact-finding conference is determined to be necessary by the Department or is requested by a person seeking good cause standing, the parties to the case shall include only the applicant, any person showing good cause, *and* any third-party payor providing health care insurance or prepaid coverage to five percent or more of the patients in the applicant's service area~~, and the relevant health planning agency~~.

~~E~~*G.* Upon entry of each completed application or applications into the appropriate batch review cycle:

1. The Department shall establish, for every application, a date between the ~~eightieth~~ *tenth* and ~~ninetieth~~ *twentieth* calendar days within the ~~190-calendar-day~~*120-calendar-day* review period for holding an informal fact-finding conference, if such conference is necessary.

2. The Department shall review every application at or before the ~~seventy-fifth~~ *fifth* calendar day within the ~~190-calendar-day~~*120-calendar-day* review period to determine whether an informal fact-finding conference is necessary.

3. Any person seeking to be made a party to the case for good cause shall notify the Department of his request and the basis therefor on or before the ~~eightieth~~ *tenth* calendar day following the day which begins the appropriate batch review cycle.

4. In any case in which an informal fact-finding conference is held, a date shall be established for the closing of the record which shall not be more than 30 calendar days after the date for holding the informal fact-finding conference.

5. In any case in which an informal fact-finding conference is not held, the record shall be closed on the earlier of (i) the date established for holding the informal fact-finding conference or (ii) the date that the Department determines an informal fact-finding conference is not necessary.

6. ~~The provisions of subsection D of § 2.2-4019 notwithstanding, if~~ *If* a determination whether a public need exists for a project is not made by the Commissioner within 45 calendar days of the closing of the record, the Commissioner shall notify the applicant or applicants and any persons seeking to show good cause, in writing, that the application or the application of each shall be deemed approved 25 calendar days after expiration of such 45-calendar-day period, unless the receipt of recommendations from the person performing the hearing officer functions permits the Commissioner to issue his case decision within that 25-calendar-day period. The validity or timeliness of the aforementioned notice shall not, in any event, prevent, delay or otherwise impact the effectiveness of subdivision E 6 of § 32.1-102.6.

7. In any case when a determination as to whether a public need exists for a project is not made by the Commissioner within 70 calendar days after the closing of the record, the application shall be deemed to be approved and the certificate shall be granted.

8. If a determination as to whether a public need exists for a project is not made by the Commissioner within 45 calendar days of the closing of the record, any applicant who is competing in the relevant batch or who has filed an application in response to the relevant Request For Applications issued pursuant to § 32.1-102.3:2 may, prior to the application being deemed approved, petition for immediate injunctive relief pursuant to § 2.2-4030, naming as respondents the Commissioner and all parties to the case. During the pendency of the proceeding, no applications shall be deemed to be approved. In such a proceeding, the provisions of § 2.2-4030 shall apply.

~~F~~*H.* Deemed approvals shall be construed as the Commissioner's case decision on the application pursuant to the Administrative Process Act (§ 2.2-4000 et seq.) and shall be subject to judicial review on appeal as the Commissioner's case decision in accordance with such act.

Any person who has sought to participate in the Department's review of such deemed-to-be-approved application as a person showing good cause who has not received a final determination from the Commissioner concerning such attempt to show good cause shall be deemed to be a person showing good cause for purposes of appeal of the deemed approval of the certificate.

In any appeal of the Commissioner's case decision granting a certificate of public need pursuant to a Request for Applications issued pursuant to § 32.1-102.3:2, the court may require the appellant to file a bond pursuant to § 8.01-676.1, in such sum as shall be fixed by the court for protection of all parties interested in the case decision, conditioned on the payment of all damages and costs incurred in

consequence of such appeal.

~~G~~*I*. For purposes of this section, "good cause" shall mean that (i) there is significant relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing, or (iii) there is a substantial material mistake of fact or law in the Department staff's report on the application ~~or in the report submitted by the health planning agency~~.

~~H~~*J*. The project review procedures shall provide for separation of the project review manager functions from the hearing officer functions. No person serving in the role of project review manager shall serve as a hearing officer.

~~I~~*K*. The applicants, and only the applicants, shall have the authority to extend any of the time periods specified in this section. If all applicants consent to extending any time period in this section, the Commissioner, with the concurrence of the applicants, shall establish a new schedule for the remaining time periods.

§ 32.1-102.12. Report required.

The Commissioner shall annually report to the Governor and the General Assembly on the status of Virginia's certificate of public need program. The report shall be issued by October 1 of each year and shall include, but need not be limited to:

1. A summary of the Commissioner's actions during the previous fiscal year pursuant to this article;

2. A five-year schedule for analysis of all project categories which provides for analysis of at least three project categories per year;

3. An analysis of the appropriateness of continuing the certificate of public need program for at least three project categories in accordance with the five-year schedule for analysis of all project categories;

4. An analysis of the effectiveness of the application review procedures used by ~~the health systems agencies and~~ the Department required by § 32.1-102.6 which details the review time required during the past year for various project categories, the number of contested or opposed applications and the project categories of these contested or opposed projects, ~~the number of applications upon which the health systems agencies have failed to act in accordance with the timelines of § 32.1-102.6 B, and~~ the number of deemed approvals from the Department because of their failure to comply with the timelines required by *subsection G of* § 32.1-102.6 ~~E~~, and any other data determined by the Commissioner to be relevant to the efficient operation of the program;

5. An analysis of health care market reform in the Commonwealth and the extent, if any, to which such reform obviates the need for the certificate of public need program;

6. An analysis of the accessibility by the indigent to care provided by the medical care facilities regulated pursuant to this article and the relevance of this article to such access;

7. An analysis of the relevance of this article to the quality of care provided by medical care facilities regulated pursuant to this article; and

8. An analysis of equipment registrations required pursuant to § 32.1-102.1:1, including the type of equipment, whether an addition or replacement, and the equipment costs.

§ 32.1-122.05. Regional health planning agencies; boards; duties and responsibilities.

A. For the purpose of representing the interests of health planning regions and performing health planning activities at the regional level, there are hereby created such regional health planning agencies as may be designated by the Board of Health.

B. Each regional health planning agency shall be governed by a regional health planning board to be composed of not more than thirty residents of the region. The membership of the regional health planning boards shall include, but not be limited to, consumers, providers, a director of a local health department, a director of a local department of social services or welfare, a director of a community services board, a director of an area agency on aging and representatives of health care insurers, local governments, the business community and the academic community. The majority of the members of each regional health planning board shall be consumers. Consumer members shall be appointed in a manner that ensures the equitable geographic and demographic representation of the region. Provider members shall be solicited from professional organizations, service and educational institutions and associations of service providers and health care insurers in a manner that assures equitable representation of provider interest.

The members of the regional health planning boards shall be appointed for no more than two consecutive terms of four years or, when appointed to fill an unexpired term of less than four years, for three consecutive terms consisting of one term of less than four years and two terms of four years. The boards shall not be self-perpetuating. The Board of Health shall establish procedures requiring staggered terms. The composition and the method of appointment of the regional health planning boards shall be established in the regulations of the Board of Health. In addition, the Board of Health shall require, pursuant to regulations, each regional health planning board to report and maintain a record of its membership, including, but not limited to, the names, addresses, dates of appointment, years served, number of consecutive and nonconsecutive terms, and the group represented by each member. These

membership reports and records shall be public information and shall be published in accordance with the regulations of the Board.

C. An agreement shall be executed between the Commissioner, in consultation with the Board of Health, and each regional health planning board to delineate the work plan and products to be developed with state funds. Funding for the regional health planning agencies shall be contingent upon meeting these obligations and complying with the Board's regulations.

D. Each regional health planning agency shall assist the Board of Health by: (i) conducting data collection, research and analyses as required by the Board; (ii) preparing reports and studies in consultation and cooperation with the Board; (iii) reviewing and commenting on the components of the State Health Plan; (iv) conducting needs assessments as appropriate and serving as a technical resource to the Board; (v) identifying gaps in services, inappropriate use of services or resources and assessing accessibility of critical services; ~~(vi)~~ ~~reviewing~~ ~~applications~~ ~~for~~ ~~certificates~~ ~~of~~ ~~public~~ ~~need~~ ~~and~~ ~~making~~ ~~recommendations~~ ~~to~~ ~~the~~ ~~Department~~ ~~thereon~~ ~~as~~ ~~provided~~ ~~in~~ ~~§ 32.1-102.6;~~ and (~~vii~~*vi*) conducting such other functions as directed by the regional health planning board. All regional health planning agencies shall demonstrate and document accountability for state funds through annual budget projections and quarterly expenditure and activity reports that shall be submitted to the Commissioner. A regional health planning agency may designate membership and activities at subarea levels as deemed appropriate by its regional health planning board. Each regional health planning board shall adopt bylaws for its operation and for the election of its chairman and shall maintain and publish a record of its membership and any subarea levels as required by this section and the regulations of the Board of Health.