

“(B) FORMULARY DEVELOPMENT.—In developing and reviewing the formulary, the committee shall—

“(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate; and

“(ii) take into account whether including in the formulary (or in a tier in such formulary) particular covered part D drugs has therapeutic advantages in terms of safety and efficacy.

“(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES AND CLASSES.—

“(i) IN GENERAL.—The formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

“(ii) MODEL GUIDELINES.—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

“(iii) LIMITATION ON CHANGES IN THERAPEUTIC CLASSIFICATION.—The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs.

“(D) PROVIDER AND PATIENT EDUCATION.—The PDP sponsor shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

“(E) NOTICE BEFORE REMOVING DRUG FROM FORMULARY OR CHANGING PREFERRED OR TIER STATUS OF DRUG.—Any removal of a covered part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists.

“(F) PERIODIC EVALUATION OF PROTOCOLS.—In connection with the formulary, the sponsor of a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures. The requirements of this paragraph may be met by a PDP sponsor directly or through arrangements with another entity.

“(c) COST AND UTILIZATION MANAGEMENT; **QUALITY ASSURANCE;** MEDICATION THERAPY MANAGEMENT PROGRAM.—

“(1) IN GENERAL.—The PDP sponsor shall have in place, directly or through appropriate arrangements, with respect to covered part D drugs, the following:

“(A) A cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs (as defined in section 1927(k)(7)(A)(i)).

“(B) **Quality assurance measures** and systems to reduce medication errors and adverse drug interactions and improve medication use.

“(C) A medication therapy management program described in paragraph (2).

“(D) A program to control fraud, abuse, and waste. Nothing in this section shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation.

“(2) MEDICATION THERAPY MANAGEMENT PROGRAM.—

“(A) DESCRIPTION.—

“(i) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries described in clause

(ii), that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Such a program may distinguish between services in ambulatory and institutional settings.

“(ii) TARGETED BENEFICIARIES DESCRIBED.—Targeted beneficiaries described in this clause are part D eligible individuals who—

“(I) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

“(II) are taking multiple covered part D drugs; and

“(III) are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary.

“(B) ELEMENTS.—Such program may include elements that promote—

“(i) enhanced enrollee understanding to promote the appropriate use of medications by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, and other appropriate means;

“(ii) increased enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and

“(iii) detection of adverse drug events and patterns of overuse and under use of prescription drugs.

“(C) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—Such program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

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“(D) COORDINATION WITH CARE MANAGEMENT PLANS.—The Secretary shall establish guidelines for the coordination

of any medication therapy management program under this paragraph with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program under section 1807.

“(E) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a prescription drug plan shall take into account, in establishing fees for pharmacists and others providing services under such plan, the resources used, and time required to, implement the medication therapy management program under this paragraph. Each such sponsor shall disclose to the Secretary upon request the amount of any such management or dispensing fees. The provisions of section 1927(b)(3)(D) apply to information disclosed under this subparagraph.

“(d) CONSUMER SATISFACTION SURVEYS.—In order to provide for comparative information under section 1860D–1(c)(3)(A)(v), the Secretary shall conduct consumer satisfaction surveys with respect to PDP sponsors and prescription drug plans in a manner similar to the manner such surveys are conducted for MA organizations and MA plans under part C.

“(e) ELECTRONIC PRESCRIPTION PROGRAM.—

“(1) APPLICATION OF STANDARDS.—As of such date as the Secretary may specify, but not later than 1 year after the date of promulgation of final standards under paragraph (4)(D), prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2).

“(2) PROGRAM REQUIREMENTS.—Consistent with uniform standards established under paragraph (3)—

“(A) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL AND DISPENSING PHARMACIES AND PHARMACISTS.—An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:

“(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

“(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

“(B) APPLICATION TO MEDICAL HISTORY INFORMATION.—Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to

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carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related

to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

“(C) LIMITATIONS.—Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

“(D) TIMING.—To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

“(3) STANDARDS.—

“(A) IN GENERAL.—The Secretary shall provide consistent with this subsection for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs under paragraph (2).

“(B) OBJECTIVES.—Such standards shall be consistent with the objectives of improving—

“(i) patient safety;

“(ii) the quality of care provided to patients; and

“(iii) efficiencies, including cost savings, in the delivery of care.

“(C) DESIGN CRITERIA.—Such standards shall—

“(i) be designed so that, to the extent practicable, the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists;

“(ii) be compatible with standards established under part C of title XI, standards established under subsection (b)(2)(B)(i), and with general health information technology standards; and

“(iii) be designed so that they permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the National Library of Medicine.

“(D) PERMITTING USE OF APPROPRIATE MESSAGING.—

Such standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B).

“(E) PERMITTING PATIENT DESIGNATION OF DISPENSING PHARMACY.—

“(i) IN GENERAL.—Consistent with clause (ii), such standards shall permit a part D eligible individual to designate a particular pharmacy to dispense a prescribed drug.

“(ii) NO CHANGE IN BENEFITS.—Clause (i) shall not be construed as affecting—

“(I) the access required to be provided to pharmacies by a prescription drug plan; or

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“(II) the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a covered part D drug.

“(4) DEVELOPMENT, PROMULGATION, AND MODIFICATION OF STANDARDS.—

“(A) INITIAL STANDARDS.—Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or modify initial uniform standards relating to the requirements

for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations(if any) from the National Committee on Vital and Health Statistics (as established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k))) under subparagraph (B).

“(B) ROLE OF NCVHS.—The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

“(i) Standard setting organizations (as defined in section 1171(8))

“(ii) Practicing physicians.

“(iii) Hospitals.

“(iv) Pharmacies.

“(v) Practicing pharmacists.

“(vi) Pharmacy benefit managers.

“(vii) State boards of pharmacy.

“(viii) State boards of medicine.

“(ix) Experts on electronic prescribing.

“(x) Other appropriate Federal agencies.

“(C) PILOT PROJECT TO TEST INITIAL STANDARDS.—

“(i) IN GENERAL.—During the 1-year period that begins on January 1, 2006, the Secretary shall conduct a pilot project to test the initial standards developed under subparagraph (A) prior to the promulgation of the final uniform standards under subparagraph (D) in order to provide for the efficient implementation of the requirements described in paragraph (2).

“(ii) EXCEPTION.—Pilot testing of standards is not required under clause (i) where there already is adequate industry experience with such standards, as determined by the Secretary after consultation with effected standard setting organizations and industry users.

“(iii) VOLUNTARY PARTICIPATION OF PHYSICIANS AND PHARMACIES.—In order to conduct the pilot project under clause (i), the Secretary shall enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards.

“(iv) EVALUATION AND REPORT.—

“(I) EVALUATION.—The Secretary shall conduct an evaluation of the pilot project conducted under clause (i).

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“(II) REPORT TO CONGRESS.—Not later than April 1, 2007, the Secretary shall submit to Congress a report on the evaluation conducted under subclause (I).

“(D) FINAL STANDARDS.—Based upon the evaluation of the pilot project under subparagraph (C)(iv)(I) and not later than April 1, 2008, the Secretary shall promulgate uniform standards relating to the requirements described in paragraph (2).

“(5) RELATION TO STATE LAWS.—The standards promulgated under this subsection shall supersede any State law or regulation that—

“(A) is contrary to the standards or restricts the ability to carry out this part; and

“(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

“(6) ESTABLISHMENT OF SAFE HARBOR.—The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128B(b) and an exception to the prohibition under subsection (a)(1) of section 1877 with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection—

“(A) in the case of a hospital, by the hospital to members of its medical staff;

“(B) in the case of a group practice (as defined in section 1877(h)(4)), by the practice to prescribing health care professionals who are members of such practice; and

“(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization, and to prescribing health care professionals.

“(f) GRIEVANCE MECHANISM.—Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1852(f).

“(g) COVERAGE DETERMINATIONS AND RECONSIDERATIONS.—

“(1) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.—A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an MA organization with respect to benefits it offers under an MA plan under part C.

“(2) REQUEST FOR A DETERMINATION FOR THE TREATMENT OF TIERED FORMULARY DRUG.—In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, a part D eligible individual who is enrolled in the

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plan may request an exception to the tiered cost-sharing structure. Under such an exception, a nonpreferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both. A PDP sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the Secretary for making a determination with respect to such a request. Denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h).

“(h) APPEALS.—

“(1) IN GENERAL.—Subject to paragraph (2), a PDP sponsor

shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to benefits (including a determination related to the application of tiered cost-sharing described in subsection (g)(2)) in a manner similar (as determined by the Secretary) to the manner such requirements apply to an MA organization with respect to benefits under the original medicare fee-for-service program option it offers under an MA plan under part C. In applying this paragraph only the part D eligible individual shall be entitled to bring such an appeal.

“(2) LIMITATION IN CASES ON NONFORMULARY DETERMINATIONS.—

A part D eligible individual who is enrolled in a prescription drug plan offered by a PDP sponsor may appeal under paragraph (1) a determination not to provide for coverage of a covered part D drug that is not on the formulary under the plan only if the prescribing physician determines that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.

“(3) TREATMENT OF NONFORMULARY DETERMINATIONS.—If a PDP sponsor determines that a plan provides coverage for a covered part D drug that is not on the formulary of the plan, the drug shall be treated as being included on the formulary for purposes of section 1860D–2(b)(4)(C)(i).

“(i) PRIVACY, CONFIDENTIALITY, AND ACCURACY OF ENROLLEE RECORDS.—The provisions of section 1852(h) shall apply to a PDP sponsor and prescription drug plan in the same manner as it applies to an MA organization and an MA plan.

“(j) TREATMENT OF ACCREDITATION.—Subparagraph (A) of section 1852(e)(4) (relating to treatment of accreditation) shall apply to a PDP sponsor under this part with respect to the following requirements, in the same manner as it applies to an MA organization with respect to the requirements in subparagraph (B) (other than clause (vii) thereof) of such section:

“(1) Subsection (b) of this section (relating to access to covered part D drugs).

“(2) Subsection (c) of this section (including quality assurance and medication therapy management).

“(3) Subsection (i) of this section (relating to confidentiality and accuracy of enrollee records).

“(k) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—

“(1) IN GENERAL.—A PDP sponsor offering a prescription drug plan shall provide that each pharmacy that dispenses

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a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

“(2) TIMING OF NOTICE.—

“(A) IN GENERAL.—Subject to subparagraph (B), the information under paragraph (1) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

“(B) WAIVER.—The Secretary may waive subparagraph (A) in such circumstances as the Secretary may specify.

“Subpart 2—Prescription Drug Plans; PDP Sponsors; Financing

“PDP REGIONS; SUBMISSION OF BIDS; PLAN APPROVAL

“SEC. 1860D–11. (a) ESTABLISHMENT OF PDP REGIONS; SERVICE AREAS.—

“(1) COVERAGE OF ENTIRE PDP REGION.—The service area for a prescription drug plan shall consist of an entire PDP region established under paragraph (2).

“(2) ESTABLISHMENT OF PDP REGIONS.—

“(A) IN GENERAL.—The Secretary shall establish, and may revise, PDP regions in a manner that is consistent with the requirements for the establishment and revision of MA regions under subparagraphs (B) and (C) of section 1858(a)(2).

“(B) RELATION TO MA REGIONS.—To the extent practicable, PDP regions shall be the same as MA regions under section 1858(a)(2). The Secretary may establish PDP regions which are not the same as MA regions if the Secretary determines that the establishment of different regions under this part would improve access to benefits under this part.

“(C) AUTHORITY FOR TERRITORIES.—The Secretary shall establish, and may revise, PDP regions for areas in States that are not within the 50 States or the District of Columbia.

“(3) NATIONAL PLAN.—Nothing in this subsection shall be construed as preventing a prescription drug plan from being offered in more than one PDP region (including all PDP regions).

“(b) SUBMISSION OF BIDS, PREMIUMS, AND RELATED INFORMATION.—

“(1) IN GENERAL.—A PDP sponsor shall submit to the Secretary information described in paragraph (2) with respect to each prescription drug plan it offers. Such information shall be submitted at the same time and in a similar manner to the manner in which information described in paragraph (6) of section 1854(a) is submitted by an MA organization under paragraph (1) of such section.

“(2) INFORMATION DESCRIBED.—The information described in this paragraph is information on the following:

“(A) COVERAGE PROVIDED.—The prescription drug coverage provided under the plan, including the deductible and other cost-sharing.

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“(B) ACTUARIAL VALUE.—The actuarial value of the qualified prescription drug coverage in the region for a part D eligible individual with a national average risk profile for the factors described in section 1860D–15(c)(1)(A) (as specified by the Secretary).

“(C) BID.—Information on the bid, including an actuarial certification of—

“(i) the basis for the actuarial value described in subparagraph (B) assumed in such bid;

“(ii) the portion of such bid attributable to basic prescription drug coverage and, if applicable, the portion of such bid attributable to supplemental benefits;

“(iii) assumptions regarding the reinsurance subsidy payments provided under section 1860D–15(b)

subtracted from the actuarial value to produce such bid; and

“(iv) administrative expenses assumed in the bid.

“(D) SERVICE AREA.—The service area for the plan.

“(E) LEVEL OF RISK ASSUMED.—

“(i) IN GENERAL.—Whether the PDP sponsor requires a modification of risk level under clause (ii) and, if so, the extent of such modification. Any such modification shall apply with respect to all prescription drug plans offered by a PDP sponsor in a PDP region. This subparagraph shall not apply to an MA–PD plan.

“(ii) RISK LEVELS DESCRIBED.—A modification of risk level under this clause may consist of one or more of the following:

“(I) INCREASE IN FEDERAL PERCENTAGE ASSUMED IN INITIAL RISK CORRIDOR.—An equal percentage point increase in the percents applied under subparagraphs (B)(i), (B)(ii)(I), (C)(i), and (C)(ii)(I) of section 1860D–15(e)(2). In no case shall the application of previous sentence prevent the application of a higher percentage under section 1869D–15(e)(2)(B)(iii).

“(II) INCREASE IN FEDERAL PERCENTAGE ASSUMED IN SECOND RISK CORRIDOR.—An equal percentage point increase in the percents applied under subparagraphs (B)(ii)(II) and (C)(ii)(II) of section 1860D–15(e)(2).

“(III) DECREASE IN SIZE OF RISK CORRIDORS.—A decrease in the threshold risk percentages specified in section 1860D–15(e)(3)(C).

“(F) ADDITIONAL INFORMATION.—Such other information as the Secretary may require to carry out this part.

“(3) PAPERWORK REDUCTION FOR OFFERING OF PRESCRIPTION DRUG PLANS NATIONALLY OR IN MULTI-REGION AREAS.—The Secretary shall establish requirements for information submission under this subsection in a manner that promotes the offering of such plans in more than one PDP region (including all regions) through the filing of consolidated information.

“(c) ACTUARIAL VALUATION.—

“(1) PROCESSES.—For purposes of this part, the Secretary shall establish processes and methods for determining the actuarial valuation of prescription drug coverage, including—

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“(A) an actuarial valuation of standard prescription drug coverage under section 1860D–2(b);

“(B) actuarial valuations relating to alternative prescription drug coverage under section 1860D–2(c)(1);

“(C) an actuarial valuation of the reinsurance subsidy payments under section 1860D–15(b);

“(D) the use of generally accepted actuarial principles and methodologies; and

“(E) applying the same methodology for determinations of actuarial valuations under subparagraphs (A) and (B).

“(2) ACCOUNTING FOR DRUG UTILIZATION.—Such processes and methods for determining actuarial valuation shall take into account the effect that providing alternative prescription drug coverage (rather than standard prescription drug coverage) has on drug utilization.

“(3) RESPONSIBILITIES.—

“(A) PLAN RESPONSIBILITIES.—PDP sponsors and MA

organizations are responsible for the preparation and submission of actuarial valuations required under this part for prescription drug plans and MA–PD plans they offer.

“(B) USE OF OUTSIDE ACTUARIES.—Under the processes and methods established under paragraph (1), PDP sponsors offering prescription drug plans and MA organizations offering MA–PD plans may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values.

“(d) REVIEW OF INFORMATION AND NEGOTIATION.—

“(1) REVIEW OF INFORMATION.—The Secretary shall review the information filed under subsection (b) for the purpose of conducting negotiations under paragraph (2).

“(2) NEGOTIATION REGARDING TERMS AND CONDITIONS.—Subject to subsection (i), in exercising the authority under paragraph (1), the Secretary—

“(A) has the authority to negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan; and

“(B) has authority similar to the authority of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5, United States Code.

“(e) APPROVAL OF PROPOSED PLANS.—

“(1) IN GENERAL.—After review and negotiation under subsection (d), the Secretary shall approve or disapprove the prescription drug plan.

“(2) REQUIREMENTS FOR APPROVAL.—The Secretary may approve a prescription drug plan only if the following requirements are met:

“(A) COMPLIANCE WITH REQUIREMENTS.—The plan and the PDP sponsor offering the plan comply with the requirements under this part, including the provision of qualified prescription drug coverage.

“(B) ACTUARIAL DETERMINATIONS.—The Secretary determines that the plan and PDP sponsor meet the requirements under this part relating to actuarial determinations, including such requirements under section 1860D–2(c).

“(C) APPLICATION OF FEHBP STANDARD.—

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“(i) IN GENERAL.—The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to basic prescription drug coverage is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section 1860D–15(b).

“(ii) SUPPLEMENTAL COVERAGE.—The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to supplemental prescription drug coverage pursuant to section 1860D–2(a)(2) is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act)

for such coverage under the plan.

“(D) PLAN DESIGN.—

“(i) IN GENERAL.—The Secretary does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.

“(ii) USE OF CATEGORIES AND CLASSES IN FORMULARIES.—The Secretary may not find that the design of categories and classes within a formulary violates clause (i) if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.

“(f) APPLICATION OF LIMITED RISK PLANS.—

“(1) CONDITIONS FOR APPROVAL OF LIMITED RISK PLANS.—The Secretary may only approve a limited risk plan (as defined in paragraph (4)(A)) for a PDP region if the access requirements under section 1860D–3(a) would not be met for the region but for the approval of such a plan (or a fallback prescription drug plan under subsection (g)).

“(2) RULES.—The following rules shall apply with respect to the approval of a limited risk plan in a PDP region:

“(A) LIMITED EXERCISE OF AUTHORITY.—Only the minimum number of such plans may be approved in order to meet the access requirements under section 1860D–3(a).

“(B) MAXIMIZING ASSUMPTION OF RISK.—The Secretary shall provide priority in approval for those plans bearing the highest level of risk (as computed by the Secretary), but the Secretary may take into account the level of the bids submitted by such plans.

“(C) NO FULL UNDERWRITING FOR LIMITED RISK PLANS.—In no case may the Secretary approve a limited risk plan under which the modification of risk level provides for no (or a de minimis) level of financial risk.

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“(3) ACCEPTANCE OF ALL FULL RISK CONTRACTS.—There shall be no limit on the number of full risk plans that are approved under subsection (e).

“(4) RISK-PLANS DEFINED.—For purposes of this subsection:

“(A) LIMITED RISK PLAN.—The term ‘limited risk plan’ means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in subparagraph (E) of subsection (b)(2) in its bid submitted for the plan under such subsection. Such term does not include a fallback prescription drug plan.

“(B) FULL RISK PLAN.—The term ‘full risk plan’ means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

“(g) GUARANTEEING ACCESS TO COVERAGE.—

“(1) SOLICITATION OF BIDS.—

“(A) IN GENERAL.—Separate from the bidding process under subsection (b), the Secretary shall provide for a process for the solicitation of bids from eligible fallback entities (as defined in paragraph (2)) for the offering in all fallback service areas (as defined in paragraph (3)) in one or more PDP regions of a fallback prescription

drug plan (as defined in paragraph (4)) during the contract period specified in paragraph (5).

“(B) ACCEPTANCE OF BIDS.—

“(i) IN GENERAL.—Except as provided in this subparagraph, the provisions of subsection (e) shall apply with respect to the approval or disapproval of fallback prescription drug plans. The Secretary shall enter into contracts under this subsection with eligible fallback entities for the offering of fallback prescription drug plans so approved in fallback service areas.

“(ii) LIMITATION OF 1 PLAN FOR ALL FALLBACK SERVICE AREAS IN A PDP REGION.—With respect to all fallback service areas in any PDP region for a contract period, the Secretary shall approve the offering of only 1 fallback prescription drug plan.

“(iii) COMPETITIVE PROCEDURES.—Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) shall be used to enter into a contract under this subsection. The provisions of subsection (d) of section 1874A shall apply to a contract under this section in the same manner as they apply to a contract under such section.

“(iv) TIMING.—The Secretary shall approve a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans would otherwise be offered.

“(V) NO NATIONAL FALLBACK PLAN.—The Secretary shall not enter into a contract with a single fallback entity for the offering of fallback plans throughout the United States.

“(2) ELIGIBLE FALLBACK ENTITY.—For purposes of this section, the term ‘eligible fallback entity’ means, with respect

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to all fallback service areas in a PDP region for a contract period, an entity that—

“(A) meets the requirements to be a PDP sponsor (or would meet such requirements but for the fact that the entity is not a risk-bearing entity); and

“(B) does not submit a bid under section 1860D–11(b) for any prescription drug plan for any PDP region for the first year of such contract period.

For purposes of subparagraph (B), an entity shall be treated as submitting a bid with respect to a prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

“(3) FALLBACK SERVICE AREA.—For purposes of this subsection, the term ‘fallback service area’ means, for a PDP region with respect to a year, any area within such region for which the Secretary determines before the beginning of the year that the access requirements of the first sentence of section 1860D–3(a) will not be met for part D eligible individuals residing in the area for the year.

“(4) FALLBACK PRESCRIPTION DRUG PLAN.—For purposes of this part, the term ‘fallback prescription drug plan’ means

a prescription drug plan that—

“(A) only offers the standard prescription drug coverage and access to negotiated prices described in section 1860D–2(a)(1)(A) and does not include any supplemental prescription drug coverage; and

“(B) meets such other requirements as the Secretary may specify.

“(5) PAYMENTS UNDER THE CONTRACT.—

“(A) IN GENERAL.—A contract entered into under this subsection shall provide for—

“(i) payment for the actual costs (taking into account negotiated price concessions described in section 1860D–2(d)(1)(B)) of covered part D drugs provided to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

“(ii) payment of management fees that are tied to performance measures established by the Secretary for the management, administration, and delivery of the benefits under the contract.

“(B) PERFORMANCE MEASURES.—The performance measures established by the Secretary pursuant to subparagraph (A)(ii) shall include at least measures for each of the following:

“(i) COSTS.—The entity contains costs to the Medicare Prescription Drug Account and to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

“(ii) QUALITY PROGRAMS.—The entity provides such enrollees with quality programs that avoid adverse drug reactions and over utilization and reduce medical errors.

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“(iii) CUSTOMER SERVICE.—The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

“(iv) BENEFIT ADMINISTRATION AND CLAIMS ADJUDICATION.—The entity provides efficient and effective benefit administration and claims adjudication.

“(6) MONTHLY BENEFICIARY PREMIUM.—Except as provided in section 1860D–13(b) (relating to late enrollment penalty) and subject to section 1860D–14 (relating to low-income assistance), the monthly beneficiary premium to be charged under a fallback prescription drug plan offered in all fallback service areas in a PDP region shall be uniform and shall be equal to 25.5 percent of an amount equal to the Secretary’s estimate of the average monthly per capita actuarial cost, including administrative expenses, under the fallback prescription drug plan of providing coverage in the region, as calculated by the Chief Actuary of the Centers for Medicare & Medicaid Services. In calculating such administrative expenses, the Chief Actuary shall use a factor that is based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

“(7) GENERAL CONTRACT TERMS AND CONDITIONS.—

“(A) IN GENERAL.—Except as may be appropriate to carry out this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans under this subsection shall be the same as the terms and conditions of contracts under this part for prescription drug plans.

“(B) PERIOD OF CONTRACT.—

“(i) IN GENERAL.—Subject to clause (ii), a contract approved for a fallback prescription drug plan for fallback service areas for a PDP region under this section shall be for a period of 3 years (except as may be renewed after a subsequent bidding process).

“(ii) LIMITATION.—A fallback prescription drug plan may be offered under a contract in an area for a year only if that area is a fallback service area for that year.

“(C) ENTITY NOT PERMITTED TO MARKET OR BRAND FALLBACK PRESCRIPTION DRUG PLANS.—An eligible fallback entity with a contract under this subsection may not engage in any marketing or branding of a fallback prescription drug plan.

“(h) ANNUAL REPORT ON USE OF LIMITED RISK PLANS AND FALLBACK PLANS.—The Secretary shall submit to Congress an annual report that describes instances in which limited risk plans and fallback prescription drug plans were offered under subsections (f) and (g). The Secretary shall include in such report such recommendations as may be appropriate to limit the need for the provision of such plans and to maximize the assumption of financial risk under section subsection (f).

“(i) NONINTERFERENCE.—In order to promote competition under this part and in carrying out this part, the Secretary—

“(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and

“(2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

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is amended by inserting “(which for purposes of this subparagraph does not include a nurse practitioner)” after “attending physician (as defined in section 1861(dd)(3)(B))”.

SEC. 409. RURAL HOSPICE DEMONSTRATION PROJECT.

(a) IN GENERAL.—The Secretary shall conduct a demonstration project for the delivery of hospice care to medicare beneficiaries in rural areas. Under the project medicare beneficiaries who are unable to receive hospice care in the facility for lack of an appropriate caregiver are provided such care in a facility of 20 or fewer beds which offers, within its walls, the full range of services provided by hospice programs under section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)).

(b) SCOPE OF PROJECT.—The Secretary shall conduct the project under this section with respect to no more than 3 hospice programs over a period of not longer than 5 years each.

(c) COMPLIANCE WITH CONDITIONS.—Under the demonstration project—

(1) the hospice program shall comply with otherwise applicable requirements, except that it shall not be required to offer services outside of the home or to meet the requirements of section 1861(dd)(2)(A)(iii) of the Social Security Act; and

(2) payments for hospice care shall be made at the rates otherwise applicable to such care under title XVIII of such Act.

The Secretary may require the program to comply with such additional **quality assurance standards** for its provision of services in its facility as the Secretary deems appropriate.

(d) REPORT.—Upon completion of the project, the Secretary shall submit a report to Congress on the project and shall include in the report recommendations regarding extension of such project

to hospice programs serving rural areas.

SEC. 410. EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES FROM THE PROSPECTIVE PAYMENT SYSTEM FOR SKILLED NURSING FACILITIES.

(a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C. 1395yy(e)(2)(A)) is amended—

(1) in clause (i)(II), by striking “clauses (ii) and (iii)” and inserting “clauses (ii), (iii), and (iv)”;

(2) by adding at the end the following new clause:

“(iv) EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES.— Services described in this clause are—

“(I) rural health clinic services (as defined in paragraph (1) of section 1861(aa)); and

“(II) federally qualified health center services (as defined in paragraph (3) of such section); that would be described in clause (ii) if such services were furnished by an individual not affiliated with a rural health clinic or a federally qualified health center.”.

(b) EFFECTIVE DATE.—The amendments made by subsection

(a) shall apply to services furnished on or after January 1, 2005.