The MBS Report on Regulatory Mandates in the Medicare Modernization Act of 2000

A. Mandates Imposed on the Health Care Finance Administration.

1. New Competitive Benefit Package; Establishment of Premiums.

(1) Establishment of normalized bids. Convert each Medicare+Choice plan's original bid into a normalized bid by adjusting for the relative risk of enrollees based on health status and demographic adjustment factors. See MMA § 101(a)(4), proposed SSA § 1853(d)(1)(A) (p. 9).

(2) Establishment of benchmark amounts. Establish a plan benchmark amount for each plan using the plan's enrollment assumptions. See MMA § 101(a)(4), proposed SSA § 1853(d)(2)(A) (p. 10).

(3) Establishment of monthly payment amounts. Compare each plan's normalized bid with the benchmark amount for the plan, and establish the monthly payment amount (*i.e.*, to be paid by HCFA to the plan) based on the lower of the two. See MMA § 101(a)(4), proposed SSA § 1853(d)(2)(B) (pp. 10-11).

(4) Methodology for bid adjustments. Promulgate a regulation setting forth the methodology for adjusting the bids of Medicare+Choice organizations, for establishing benchmark amounts, and for establishing monthly premiums. See MMA § 101(a)(2), proposed SSA § 1853(b)(4) (pp. 3-7).

(5) Form and content of bids. Promulgate a regulation setting forth the form and content of Medicare+Choice normalized bids. See MMA § 101(a)(2), proposed SSA § 1853(b)(4) (pp. 3-7).

(6) Separate bid calculations for different populations. Calculate the bid adjustment factors separately for benefits under Parts A and B combined, and for benefits under Part D; as well as separately for aged and disabled beneficiaries, and beneficiaries with end-stage renal disease, pending establishment of an integrated risk adjustment system. See MMA § 101(a), proposed SSA § 1853(b)(4) (p. 4).

(7) Establishment of additional adjustment factors. Promulgate a regulation establishing additional health status and demographic adjustment factors to be applied in adjusting premium bids. See MMA § 101(a)(2), proposed SSA § 1853(b)(4)(D) (pp. 6-7).

(8) Establishment of integrated risk adjustment system. Establish an "integrated risk adjustment system" to be applied when making premium determinations for beneficiaries who are aged or disabled or who have end-stage renal disease. See MMA § 101(a)(2), proposed SSA § 1853(b)(4)(A) (flush language) (p. 4).

(9) Determination of annual monthly premiums. Determine the annual monthly premium reduction or monthly excess premium amount for each Medicare+Choice plans' enrollees by subtracting the plan's normalized bid from the plan's benchmark amount and making adjustments according to the statutory formula. See MMA § 101(b)(1), proposed SSA § 1854(c) (pp. 11-12).

(10) Actuarial comparisons in connection with premium determinations. In making premium determinations for Medicare+Choice plans, ensure that the actuarial value of deductibles, coinsurance, copayments, cost sharing reductions, and supplemental premiums applicable to enrollees is equal to the actuarial value of deductibles, coinsurance, and copayments that would apply if the enrollees were not members of Medicare+Choice plans, taking into account geographic differences, plan costs, and utilization differences. See MMA § 101(b)(2), proposed SSA § 1854(e)(1) (pp. 12-13).

(11) Technical requirements for actuarial determinations. Establish, in the form of guidance or through promulgation of a regulation, technical guidelines on the mechanics of how to apply or adjust geographic differences, plan costs, and utilization differences for use in comparing proposed plan premiums under Medicare+Choice plans with premiums under the traditional Medicare program. See MMA § 101(b)(2), proposed SSA § 1854(e)(1) (pp. 12-13).

(12) Administrative review of challenges to premium and/or cost sharing determinations. Provide an opportunity for administrative review of premium and/or cost sharing determinations, including a petition process and administrative hearings. See MMA § 101(a), (b) , proposed SSA §§ 1853(d), 1854(c) (pp. 10-12).

(13) Judicial review of premium and/or cost sharing determinations. Defend challenges to administrative determinations regarding the validity and appropriateness of premium and/or cost sharing determinations. See MMA § 101(a), (b) , proposed SSA §§ 1853(d), 1854(c) (pp. 10-12).

2. Coordination of Care Program.

(14) Criteria for eligible enrollees. Promulgate a regulation setting forth the criteria for determining which individuals may appropriately be enrolled in the care coordination services program. See MMA § 111, proposed SSA § 1866A(b)(1) (p. 19).

(15) Individualized enrollee eligibility determinations. Determine the eligibility of individual applicants for inclusion in the care coordination services program. See MMA § 111, proposed SSA § 1866A(b)(1), (c)(1) (pp. 19-20).

(16) Eligibility cohorts. Determine which "cohorts" of individuals have characteristics identified by HCFA such that professional management and coordination of care can reasonably be expected to improve health care processes or outcomes and reduce aggregate costs to the Medicare program. See MMA § 111, proposed SSA § 1866A(b)(1) (p. 19).

(17) Enrollment facilitation procedures. Promulgate a regulation establishing procedures to facilitate the enrollment of eligible individuals in the care coordination services program. See MMA § 111, proposed SSA § 1866A(b)(2) (p. 19).

(18) Application process. Promulgate a regulation establishing the application process for participation in the care coordination services program. See MMA § 111, proposed SSA § 1866A(c)(1) (pp. 19-20).

(19) Assignment of individuals to specific care coordination services providers. Assign individuals (whose applications for participation in the care coordination services program have been accepted by HCFA) to specific care coordination service providers. See MMA § 111, proposed SSA § 1866A(c)(1) (pp. 19-20).

(20) Disputes over participation in program. Promulgate a regulation governing relative rights and responsibilities of health care plans and enrollees when one party wants participation in the care coordination services program and the other does not. See MMA § 111, proposed SSA § 1866A(c)(1) (pp. 19-20).

(21) Duration of participation. Promulgate a regulation governing periods of participation in the care coordination services program. See MMA § 111, proposed SSA § 1866A(c)(2)(A) (p. 20).

(22) Limit on reenrollment. Promulgate a regulation establishing limits on an individual's eligibility to reenroll in the care coordination services program if the individual has disenrolled from the program more than once during a specified period of time. See MMA § 111, proposed SSA § 1866A(c)(2)(B) (p. 20).

(23) Individualized reenrollment and termination determinations. Make individualized enrollee reenrollment or termination determinations. See MMA § 111, proposed SSA § 1866A(c)(2)(B) (p. 20).

(24) Scope of benefits. Promulgate a regulation establishing the specific benefits to be provided in the care coordination services program, including additional benefits not specified in § 1905(t)(1) in order to encourage enrollment in, or improve the effectiveness of, the program. See MMA § 111, proposed SSA § 1866A(d)(1) (pp. 20-21).

(25) Restrictions on participants. Promulgate a regulation to govern the circumstances in which the enrollee will be entitled to payment for health care items or services only if such items or services have been furnished by the care coordinator, or coordinated through the care coordination services program (including exceptions for emergencies). See MMA § 111, proposed SSA § 1866A(d)(2) (p. 21).

(26) Cost sharing elimination or reduction. Make determinations whether to reduce or eliminate beneficiary cost sharing (such as deductibles, copayments, or coinsurance) with respect to items or services provided under the care coordination services program, including whether to limit such reductions to particular service areas. See MMA § 111, proposed SSA § 1866A(d)(3) (p. 21).

(27) Criteria for provider participation. Promulgate a regulation establishing the criteria that providers must meet in order to furnish care coordination services, including recordkeeping and reporting requirements. See MMA § 111, proposed SSA § 1866A(e)(1) (pp. 21-22).

(28) Contracting with providers. Enter into "care coordination agreements" with individual care coordination service providers under which such providers will provide care coordination services. See MMA § 111, proposed SSA § 1866A(e)(2) (p. 22).

(29) Provider renewal determinations. Assess provider performance under care coordination agreements annually, and determine whether to renew such agreements. See MMA § 111, proposed SSA § 1866A(e)(2)(A) (p. 22).

(30) Provider reimbursement rates. Negotiate payment terms and rates for services with care coordination service providers. See MMA § 111, proposed SSA § 1866A(e)(2)(B) (p. 22).

(31) Performance standards for coordination of care services program. Establish performance standards for the coordination of care services program. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(32) Compliance with coordination of care performance standards. Ensure compliance by coordination of care services program participants with the performance standards. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(33) Administrative review of determinations in connection with the coordination of care services program. Provide administrative review of adverse decisions affecting participants in the coordination of care services program. See MMA §§ 111, 118(a), proposed SSA §§ 1866A(e)(2)(A), 1866M(b)(6) (pp. 22, 47-48).

(34) Marketing materials in connection with the coordination of care services program. Review and approve/disapprove marketing materials of participants in the coordination of care services program. See MMA § 118(a), proposed SSA § 1866M(b)(7) (p. 48).

(35) Contracting with outside contractors for implementation of the coordination of care services program. Select and contract with a "program administrator" to administer the coordination of care services program, and oversee proper administration by such outside contractor. See MMA § 118(a), proposed SSA § 1866M(c) (pp. 49-53).

3. Disease Management Program.

(36) Scope of coverage regulation for disease management program. Promulgate a regulation establishing which diagnoses are amenable to management pursuant to a disease management services program, taking into account whether there is evidence that the provision of disease management services, over clinically relevant time periods, to cohorts of individuals with such diagnoses can reasonably be expected to improve processes or outcomes of health care and reduce aggregate costs. See MMA § 112, proposed SSA § 1866B(a)(1), (b)(1)(A), (f)(1) (pp. 24-25, 26-27).

(37) Regulation governing additional factors for inclusion in disease management program. Promulgate a regulation establishing which additional factors could serve as predicates for the provision of disease management services, including clinical characteristics or conditions, utilization patterns, and other factors. See MMA § 112, proposed SSA § 1866B(b)(1)(B) (p. 25).

(38) Individual eligibility determinations for disease management program. Make individual enrollee eligibility determinations for participation in the disease management services program. See MMA § 112, proposed SSA § 1866B(b) (pp. 24-25).

NOTE: It is clear from the proposed statutory language that HCFA would have to make the "findings" that would trigger the eligibility of specific enrollees to participate in the program.

(39) Regulation on referrals and disagreements over participation in disease management program. Promulgate a regulation governing referrals for participation in the disease management program, including the relative rights and responsibilities of health care plans and enrollees when one party wants participation in the program and the other does not. See MMA § 112, proposed SSA § 1866B(b)(2) (p. 25).

(40) Enrollment facilitation regulation for disease management program. Promulgate a regulation to facilitate the enrollment of eligible individuals in the disease management program. See MMA § 112, proposed SSA § 1866B(c) (p. 25).

(41) Individualized assignments to particular entities. After making eligibility determinations, assign individual participants in the disease management program to specific disease management entities. See MMA § 112, proposed SSA § 1866B(d)(1) (pp. 25-26).

(42) Renewal and termination determinations in disease management program. Determine at periodic intervals whether to terminate enrollment in the disease management program. See MMA § 112, proposed SSA § 1866B(d)(1) (pp. 25-26).

(43) Regulation governing renewals and terminations in disease management program. Promulgate a regulation to govern renewals and terminations in the disease management program, including limits on an individual's eligibility to reenroll in the program if the individual has disenrolled more than once during a specified time period. See MMA § 112, proposed SSA § 1866B(d)(1), (2) (pp. 25-26).

(44) Regulation governing compulsory participation in disease management program. Promulgate a regulation establishing conditions in which a beneficiary is required to obtain health care items or services pursuant to the disease management program in order for such items or services to be covered through Medicare. See MMA § 112, proposed SSA § 1866B(e) (p. 26).

(45) Compulsory assignments to disease management entities. Make compulsory 'conscription' determinations for individuals who are to be 'required' to obtain health care items or services from disease management entities against their will. See MMA § 112, proposed SSA § 1866B(e) (p. 26).

(46) Regulation governing variations in disease management service packages. Promulgate a regulation establishing variations in disease management service packages based on types of diagnoses, conditions, patient profiles, disease management organization expertise, and other factors HCFA finds appropriate. See MMA § 112, proposed SSA § 1866B(f)(2) (p. 27).

(47) Individual determinations regarding cost sharing deductions for participation in disease management program. Make determinations whether to reduce or eliminate beneficiary cost sharing (such as deductibles, copayments, or coinsurance) with respect to items or services provided under the disease management program, including whether to limit such reductions to particular service areas. See MMA § 112, proposed SSA § 1866B(f)(3) (p. 28).

(48) Regulation concerning cost sharing reductions in connection with disease management program. Promulgate a regulation to govern the extent of reductions or eliminations of beneficiary cost sharing (such as deductibles, copayments, or coinsurance) with respect to items or services provided under the disease management program (including provisions governing the limitation of such reductions to particular service areas). See MMA § 112, proposed SSA § 1866B(f)(3) (p. 28).

(49) Regulation governing entity eligibility for participation in disease management program. Promulgate a regulation to govern which entities are qualified to enter into agreements with HCFA to provide disease management services for the Medicare program, including performance standards and other criteria to be established by HCFA. See MMA § 112, proposed SSA § 1866B(g)(1), (g)(2)(C) (pp. 28-29).

(50) Contracting with disease management entities. Enter into agreements with disease management entities setting forth entity rights and obligations in connection with the provision of disease management items and services. See MMA § 112, proposed SSA § 1866B(g)(2) (pp. 28-29).

(51) Regulation governing exemptions from competitive bidding in connection with the disease management program. Promulgate a regulation establishing the objective and uniform circumstances and conditions under which HCFA may designate an entity to provide disease management services without regard to the competitive bidding requirements of 41 U.S.C. § 5. See MMA § 112, proposed SSA § 1866B(g)(3) (p. 29).

(52) Regulation governing quality of care in connection with the disease management program. Promulgate a regulation establishing standards for, and procedures for assessing, the quality of care provided by disease management organizations, including performance, licensure, and patient satisfaction standards. See MMA § 112, proposed SSA § 1866B(h)(1) (p. 29).

(53) Compliance monitoring in connection with the disease management program. Monitor compliance of disease management entities with the quality of care standards. See MMA § 112, proposed SSA § 1866B(h)(1) (p. 29).

(54) Administrative enforcement in connection with the disease management program. Undertake administrative enforcement actions (including termination and penalty assessment proceedings) against disease management entities which fail to comply with the quality of care standards. See MMA § 112, proposed SSA § 1866B(h)(1) (p. 29).

(55) Cost management standards for the disease management program. Promulgate a regulation establishing standards for managing or reducing aggregate costs of health care items or services under the disease management program, including procedures for establishing baselines and for measuring changes in costs. See MMA § 112, proposed SSA § 1866B(h)(2) (pp. 29-30).

(56) Negotiation of reimbursement rates for the disease management program. Negotiate, or otherwise determine, payment terms and rates for services provided under the disease management program. See MMA § 112, proposed SSA § 1866B(i)(1) (p. 30).

(57) Regulation governing withholding penalties under the disease management program. Promulgate a regulation to determine the appropriateness of establishing a 10% payment withholding penalty to be applied against disease management entities that fail to comply with the performance standards. See MMA § 112, proposed SSA § 1866B(i)(2) (p. 30).

(58) Performance standards for disease management program. Establish performance standards for the disease management program. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(59) Compliance with disease management performance standards. Ensure compliance of disease management program participants with the performance standards. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(60) Administrative review of determinations in connection with the disease management program. Provide administrative review of adverse decisions affecting participants in the disease management program. See MMA § 118(a), proposed SSA § 1866M(b)(6) (pp. 47-48).

(61) Marketing materials in connection with the disease management program. Review and approve/disapprove marketing materials of participants in the disease management program. See MMA § 118(a), proposed SSA § 1866M(b)(7) (p. 48).

(62) Contracting with outside contractor for implementation of the disease management program. Select and contract with a "program administrator" to administer the disease management program, and oversee proper administration by such outside contractor. See MMA § 118(a), proposed SSA § 1866M(c) (pp. 49-53).

4. Competitive Acquisition Program.

(63) Establishment of competitive acquisition areas. Establish "competitive acquisition areas" for agreement award purposes, taking into account the availability and accessibility of individuals and entities able to furnish items and services and the estimated savings to be realized by the use of competitive acquisition. See MMA § 113(a), proposed SSA § 1866C(b) (p. 32).

(64) Implementation of bidding process for competitive acquisition program. Conduct a competition among individuals and entities for each competitive acquisition area and for each class of items and services. See MMA § 113(a), proposed SSA § 1866C(c)(1) (p. 32).

(65) Regulation governing eligibility for participation in the competitive bidding contract program. Promulgate a regulation setting forth the criteria for entering into competitive acquisition agreements with HCFA. See MMA § 113(a), proposed SSA § 1866C(c)(2) (pp. 32-33).

(66) Consideration of bids for competitive acquisition contracts. Determine whether specific individuals and entities meet the conditions for awarding competitive acquisition agreements, based on finding that the individual or entity meets the quality standards and that the aggregate amounts to be paid under the competitive acquisition agreement are expected to be less than the aggregate amounts that would otherwise be paid by the Medicare system. See MMA § 113(a), proposed SSA § 1866C(c)(2) (pp. 32-33).

(67) Regulation governing competitive acquisition contract terms. Promulgate a regulation specifying the terms and conditions to be included in competitive acquisition agreements. See MMA § 113(a), proposed SSA § 1866C(c)(3) (p. 33).

(68) Entering into competitive acquisition contracts. Enter into competitive acquisition agreements with successful bidders for such contracts. See MMA § 113(a), proposed SSA § 1866C(c)(3) (p. 33).

(69) Regulation governing renewal and termination of competitive acquisition agreements. Promulgate a regulation to govern the renewal and termination of competitive acquisition agreements. See MMA § 113(a), proposed SSA § 1866C(c)(3) (p. 33).

(70) Determinations with respect to renewal and terminations of competitive acquisition agreements. Make competitive acquisition renewal and termination determinations. See MMA § 113(a), proposed SSA § 1866C(c)(3) (p. 33).

(71) Regulation governing items and services subject to competitive acquisition. Promulgate a regulation setting forth the full range of items and services subject to competitive acquisition. See MMA § 113(a), proposed SSA § 1866C(d) (p. 33).

(72) Performance standards for competitive acquisition program. Establish performance standards for the competitive acquisition program. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(73) Compliance with competitive acquisition performance standards. Ensure the compliance of competitive acquisition program participants with the performance standards. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(74) Administrative review in connection with the competitive acquisition program. Provide administrative review of adverse decisions affecting participants in the competitive acquisition program. See MMA § 118(a), proposed SSA § 1866M(b)(6) (pp. 47-48).

(75) Marketing materials in connection with the competitive acquisition program. Review and approve/disapprove marketing materials of participants in the competitive acquisition program. See MMA § 118(a), proposed SSA § 1866M(b)(7) (p. 48).

(76) Contracting with outside contractors for implementation of the competitive acquisition program. Select and contract with a "program administrator" to administer the competitive acquisition program, and oversee proper administration by such outside contractor. See MMA § 118(a), proposed SSA § 1866M(c) (pp. 49-53).

5. Provider-Physician Collaboration Program.

(77) Contracting with provider-physician collaboration groups. Enter into agreements with specific providers, suppliers, or other individuals for the furnishing of bundled items and services in selected sites of service or related to specific medical conditions or needs for an episode of care. See MMA § 114, proposed SSA § 1866D(a)(1) (p. 34).

(78) Creation of provider-physician collaboration benefit packages. Determine which specific items and services should be subject to provider-physician collaboration agreements, including, possibly, post-hospital services. See MMA § 114, proposed SSA § 1866D(a)(1) (p. 34).

(79) Regulation governing the scope of items and services subject to provider-physician collaboration. Determine whether specific entities are qualified to provide bundled items and services pursuant to provider-physician collaboration agreements, including ability to provide services more efficiently, to provide improved coordination of care, to offer additional benefits, and to meet quality and other standards and beneficiary protections. See MMA § 114, proposed SSA § 1866D(b) (p. 34).

(80) Regulation governing participation in provider-physician collaborations. Promulgate a regulation to govern provider-physician collaborations, including the qualifications for providers, professionals, and entities; collaboration agreement terms; monitoring of performance; and penalties for noncompliance. See MMA

§ 114, proposed SSA § 1866D (pp. 34-35).

(81) Processing of provider-physician collaboration reimbursement payments. Make payments pursuant to provider-physician collaboration agreements on the basis of all-inclusive rates that are to be less than the rates that would otherwise apply had the items and services been provided on a per-item/service basis. See MMA § 114, proposed SSA § 1866D(c) (pp. 34-35).

(82) Regulation governing cost sharing reductions in connection with provider-physician collaborations. Promulgate a regulation to govern the reduction or waiver of beneficiary cost sharing, and/or the provision of additional items and/or services, when items and services are provided under provider-physician collaboration agreements. See MMA § 114, proposed SSA § 1866D(e) (p. 35).

(83) Regulation governing disclosures to beneficiaries in connection with provider-physician collaborations. Promulgate a regulation setting forth the disclosures that must be made to beneficiaries before they enter into agreements to receive items and services pursuant to provider-physician collaboration agreements, as well as the terms of agreements between beneficiaries and collaboration entities. See MMA § 114, proposed SSA § 1866D(f) (p. 35).

(84) Performance standards for provider-physician collaboration program. Establish performance standards for the provider-physician collaboration program. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(85) Compliance with provider-physician collaboration performance standards. Ensure compliance of provider-physician collaboration program participants with the performance standards. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(86) Administrative review of determinations in connection with the provider-physician collaboration program. Provide administrative review of adverse decisions affecting participants in the provider-physician collaboration program. See MMA § 118(a), proposed SSA § 1866M(b)(6) (pp. 47-48).

(87) Marketing materials in connection with the provider-physician collaboration program. Review and approve/disapprove marketing materials of participants in the provider-physician collaboration program. See MMA § 118(a), proposed SSA § 1866M(b)(7) (p. 48).

(88) Contracting with outside contractors for implementation of the provider-physician collaboration program. Select and contract with a "program administrator" to administer the provider-physician collaboration program, and oversee proper administration by such outside contractor. See MMA § 118(a), proposed SSA § 1866M(c) (pp. 49-53).

6. Preferred Participants Program.

(89) Contracting with "preferred participants." Enter into agreements for the furnishing of health care items and services by individuals and entities participating in Part A or B that provide high-quality, efficient health care. See MMA § 115(a), proposed SSA § 1866E(a)(1) (pp. 35-36).

(90) Regulation governing eligible categories of "preferred participants." Promulgate a regulation setting forth standards for assessing whether specific *categories* of individuals and entities in specific geographic service areas should be subject to the preferred participant program. See MMA § 115(a), proposed SSA § 1866E(a)(2) (p. 36).

(91) Regulation governing qualifications of "preferred participants." Promulgate a regulation to govern qualifications for participation by specific individuals and entities (within the *categories* and geographic service areas identified pursuant to mandate 90) in the preferred participants program, including an objective standard for determining which individuals and entities "provide high-quality, efficient health care." See MMA § 115(a), proposed SSA § 1866E(a)(1), (b)(1)(A) (pp. 35-36).

(92) Savings determinations in connection with the preferred participants program. Determine, through a notice-and-comment rulemaking proceeding, for each geographic service area, and for each category of individuals and entities furnishing items and services within each of those geographic service areas, whether entering into preferred participant agreements would reduce the cost and improve the quality of Medicare. See MMA § 115(a), proposed SSA § 1866E(a)(2) (p. 36).

(93) Regulation governing preferred participant contract terms. Promulgate a regulation setting forth the terms of agreements to be entered into between HCFA (or its outside contractor) and individuals or entities participating in the preferred participant program. See MMA § 115(a), proposed SSA § 1866E(b)(1)(B) (pp. 36-37).

(94) Regulation governing reimbursement rates for preferred participants. Promulgate a regulation setting forth a methodology for determining payment rates (or, a schedule of payment rates) under the preferred participant program. See MMA § 115(a), proposed SSA § 1866E(b)(1)(B) (pp. 36-37).

(95) Negotiation of preferred provider reimbursement rates. Negotiate with preferred participants to arrive at the reimbursement rates applicable to items and services offered by such preferred participants. See MMA § 115(a), proposed SSA § 1866E(b)(1)(B) (pp. 36-37).

(96) Compliance monitoring in connection with the preferred participants program. Determine annually whether specific individuals and entities participating in the preferred participant program have complied with the terms of their agreements with HCFA (or its outside contractor) such that they are entitled to elect renewal of their agreements. See MMA § 115(a), proposed SSA § 1866E(b)(2) (p. 37).

(97) Regulation for determining cost sharing reductions in connection with the preferred participants program. Promulgate a regulation setting forth objective and uniformly applicable criteria for determining the extent of beneficiary cost sharing reductions or elimination under the preferred participant program. See MMA § 115(a), proposed SSA § 1866E(c) (p. 37).

(98) Performance standards for preferred participants program. Establish performance standards for the preferred participants program. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(99) Compliance with preferred participants program performance standards. Ensure compliance of preferred participants program participants with the performance standards. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(100) Administrative review of determinations in connection with the preferred participants program. Provide administrative review of adverse decisions affecting participants in the preferred participants program. See MMA § 118(a), proposed SSA § 1866M(b)(6) (pp. 47-48).

(101) Marketing materials in connection with the preferred participants program. Review and approve/disapprove marketing materials of participants in the preferred participants program. See MMA § 118(a), proposed SSA § 1866M(b)(7) (p. 48).

(102) Contracting with outside contractors for implementation of the preferred participants program. Select and contract with a "program administrator" to administer the preferred participants program, and oversee proper administration by such outside contractor. See MMA § 118(a), proposed SSA § 1866M(c) (pp. 49-53).

7. Centers of Excellence Program.

(103) Regulation governing centers of excellence bidding process. Promulgate a regulation setting forth the competitive process by which HCFA will enter into agreements with specific hospitals or other entities for the furnishing of bundled groups of items and services related to certain surgical and non-surgical procedures furnished during an episode of care. See MMA § 116(a), proposed SSA § 1866F(a)(1) (p. 38).

(104) Regulation governing benefit inclusions in centers of excellence program. Promulgate a regulation setting forth the specific surgical and non-surgical items and services subject to inclusion in the centers of excellence program. See MMA § 116(a), proposed SSA § 1866F(a)(1), (c)(1) (pp. 38-39).

(105) Regulation governing quality standards for centers of excellence program. Promulgate a regulation setting forth performance, quality and other standards for participation in the centers of excellence program. See MMA §§ 116(a) and 118(a), proposed SSA §§ 1866F(b)(1), (b)(3) and 1866M(b)(5) (pp. 38, 46-47).

(106) Review of specific quality assurance programs in connection with the centers of excellence program. Review and approve/disapprove the quality assurance programs proposed by hospitals for implementation in connection with participation in the centers of excellence program. See MMA § 116(a), proposed SSA § 1866F(b)(2) (p. 38).

(107) Processing of reimbursements in connection with centers of excellence program. Make payments to hospitals participating in the centers of excellence program pursuant to an inclusive, bundled rating schedule. See MMA § 116(a), proposed SSA § 1866F(c)(1) (p. 39).

(108) Actuarial calculations in connection with centers of excellence program. Ensure, for each year, that the estimated amount of aggregate payments to all hospitals participating in the centers of excellence program is less than the estimated amount of aggregate payments that HCFA would otherwise make for such year, adjusted for changes to the number of individuals receiving services under the program. See

MMA § 116(a), proposed SSA § 1866F(c)(2)(A) (p. 39).

(109) Payment monitoring in connection with centers of excellence program. Ensure that, with respect to each hospital participating in the centers of excellence program, the hospital does not receive a payment that exceeds the estimated amount that the hospital would have received for providing the same items and services under the otherwise applicable Medicare reimbursement scheme. See MMA § 116(a), proposed SSA § 1866F(c)(2)(B) (p. 39).

(110) Renewal and termination determinations in connection with centers of excellence program. Determine, at least every three years, whether to renew each hospital's participation in the centers of excellence program. See MMA § 116(a), proposed SSA § 1866F(d) (p. 39).

(111) Cost sharing waiver determinations in connection with centers of excellence program. Make determinations in specific instances as to whether additional services or waiver of beneficiary cost sharing should be authorized. See MMA § 116(a), proposed SSA § 1866F(e) (p. 39).

(112) Regulation governing double coverage avoidance in connection with centers of excellence program. Promulgate a regulation to prevent double coverage of items or services offered under both the centers of excellence program and the traditional Medicare program. See MMA § 116(a), proposed SSA § 1866F(f) (p. 40).

(113) Compliance with centers of excellence performance and quality standards. Ensure compliance of centers of excellence program participants with the performance standards. See MMA §§ 116(a) and 118(a), proposed SSA §§ 1866F(b)(1), (b)(3) and 1866M(b)(5) (pp. 38, 46-47).

(114) Administrative review of determinations in connection with the centers of excellence program. Provide administrative review of adverse decisions affecting participants in the centers of excellence program. See MMA § 118(a), proposed SSA § 1866M(b)(6) (pp. 47-48).

(115) Marketing materials in connection with the centers of excellence program. Review and approve/disapprove marketing materials of participants in the centers of excellence program. See MMA § 118(a), proposed SSA § 1866M(b)(7) (p. 48).

(116) Contracting with outside contractors for implementation of the centers of excellence program. Select and contract with a "program administrator" to administer the centers of excellence program, and oversee proper administration by such outside contractor. See MMA § 118(a), proposed SSA § 1866M(c) (pp. 49-53).

8. Bonus Payments Demonstration Project.

(117) Planning and development of bonus payments demonstration project. Plan and develop a demonstration project to test the use of incentives to health care groups that encourage: (i) the coordination of care by providers, practitioners, and suppliers; (ii) investment in administrative structures and processes to ensure efficient service delivery; and (iii) reward physicians for improving health outcomes. See MMA § 117(a), proposed SSA § 1866G(a)(1) (pp. 40-41).

(118) Criteria for participation in bonus payments demonstration project. Establish criteria for health care groups eligible to participate in the demonstration project, including criteria relating to numbers of health care professionals in, and of patients served by, the group; the scope of services provided; and quality of care. See MMA § 117(a), proposed SSA § 1866G(b)(1) (pp. 41-42).

(119) Bidding for participation in the bonus demonstration project. Conduct the bidding process for participation in the bonus demonstration project. Review the applications of competing, bidding health care groups. See MMA § 117(a), proposed SSA § 1866G(b)(1) (pp. 41-42).

(120) Regulation defining "health care group." Promulgate a regulation setting forth the scope of the term "health care group" for purposes of determining eligibility to participate in the bonus payment demonstration project. See MMA § 117(a), proposed SSA § 1866G(a)(3)(B) (p. 41).

(121) Contracting with health care groups for participation in the bonus demonstration project. Enter into agreements with successfully bidding health care groups under which items and services furnished as part of the demonstration project will be reimbursable to a single entity. See MMA § 117(a), proposed SSA § 1866G(b)(2) (p. 42).

(122) Reporting requirements in connection with bonus demonstration project. Promulgate a regulation specifying the data that health care groups are to report to HCFA for purposes of monitoring and evaluating the success of the demonstration project. See MMA § 117(a), proposed SSA § 1866G(b)(3) (p. 42).

(123) Core criteria for identifying beneficiary participants in the bonus demonstration project. Specify the criteria for identifying patients of a health care group who shall be considered within the scope of the demonstration project for purposes of incentive payments and effectiveness assessment. See MMA § 117(a), proposed SSA § 1866G(c)(1) (p. 42).

(124) Additional criteria for identifying beneficiary participants in the bonus demonstration project. Establish additional criteria for the inclusion of beneficiaries within the demonstration project, possibly including frequency of contact with physicians in the health care group and other factors deemed appropriate. See MMA § 117(a), proposed SSA § 1866G(c)(2) (pp. 42-43).

(125) Notification of beneficiaries eligible for bonus payments. Ensure that each beneficiary determined to be within the scope of the demonstration project is notified of the incentives and of any applicable waiver of coverage or payment rules. See MMA § 117(a), proposed SSA § 1866G(c)(3) (p. 43).

(126) Establishment of base expenditure amounts in connection with bonus demonstration project. For each health care group participating in the demonstration project, establish a base expenditure amount, equal to the average total payments under Parts A, B, and D for patients served by the health care group on a fee-for-service basis in a base period to be determined by HCFA. See MMA § 117(a), proposed SSA § 1866G(d)(1)(A) (p. 43).

(127) Establishment of annual per capita expenditure targets in connection with bonus demonstration project. For each health care group participating in the demonstration project, establish an annual per capita expenditure target for patients determined to be within the scope of the demonstration, reflecting the base expenditure amount adjusted for risk and expected growth rates. See MMA § 117(a), proposed SSA § 1866G(d)(1)(B) (p. 43).

(128) Payment of annual core bonus payments relative to performance targets. Pay to each participating health care group an annual bonus equal to a portion of the Medicare savings realized for the year relative to the performance target. See MMA § 117(a), proposed SSA § 1866G(d)(2) (p. 43).

(129) Payment of additional bonus payments relative to outcomes. Pay to each participating health care group an additional annual bonus equal to such portion as HCFA may designate of the Medicare program savings resulting from process and patient outcome improvements attributable to activities of the group. See MMA § 117(a), proposed SSA § 1866G(d)(3) (pp. 43-44).

(130) Criteria for establishing additional bonus payments. Establish criteria, after taking evidence, for determining the additional annual bonus attributable to process and patient outcome improvements. See MMA § 117(a), proposed SSA § 1866G(d)(3) (pp. 43-44).

(131) Capping of expenditures under the bonus demonstration project. Ensure that the aggregate expenditures with respect to patients within the scope of the demonstration project do not exceed the amount that would have been expended absent the demonstration project. See MMA § 117(a), proposed SSA § 1866G(d)(4) (p. 44).

(132) Selection of demonstrations. Select ten specific demonstrations for inclusion in the project. See MMA § 117(a), proposed SSA § 1866G(e) (p. 44).

(133) Selection criteria for specific demonstrations. Establish criteria for selection of the ten specific demonstrations that will be included in the project. See MMA § 117(a), proposed SSA § 1866G(e) (p. 44).

(134) Performance standards for bonus payments demonstration project. Establish performance standards for the bonus payments for health care groups demonstration program. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(135) Compliance with bonus payments demonstration project performance standards. Ensure compliance of bonus payments for health care groups program participants with the performance standards. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(136) Administrative review of determinations in connection with bonus demonstration project. Provide administrative review of adverse decisions affecting participants in the bonus payments for health care groups program. See MMA § 118(a), proposed SSA § 1866M(b)(6) (pp. 47-48).

(137) Marketing materials in connection with bonus demonstration project. Review and approve/disapprove marketing materials of participants in the bonus payments for health care groups program. See MMA § 118(a), proposed SSA § 1866M(b)(7) (p. 48).

(138) Contracting with outside contractors for implementation of the bonus demonstration project. Select and contract with a "program administrator" to administer the bonus payments for health care groups program, and oversee proper administration by such outside contractor. See MMA § 118(a), proposed SSA § 1866M(c) (pp. 49-53).

9. Reports to Congress.

(139) Biennial report to Congress on Medicare modernization programs. Prepare a biennial report to Congress on the impact of the following programs on Medicare expenditures, access, and quality: (i) coordination of care services program; (ii) disease management services program; (iii) competitive acquisition program; (iv) provider-physician collaboration program; (v) preferred participants program; (vi) centers of excellence program; and (vii) bonus payments demonstration project. See MMA § 119 (p. 57).

10. Prescription Drug Benefit Program.

a. Enrollment.

(140) Regulation governing enrollment process. Promulgate a regulation to govern the enrollment process. See MMA § 201, proposed SSA § 1859C(a) (p. 73).

(141) Implementation of enrollment process. Enroll individuals for prescription drug coverage in accordance with the statutory enrollment deadlines. See MMA § 201, proposed SSA § 1859C(b) (pp. 73-74).

(142) Terminations of coverage. Terminate Part D coverage of individuals as of such time as they are no longer covered under Part A or B. See MMA § 201, proposed SSA § 1859C(e)(2) (p. 74).

(143) Study on feasibility of annual enrollment period. Conduct a study on the feasibility and advisability of establishing an annual open enrollment period for the Part D program. See MMA § 201, proposed SSA § 201(b) (pp. 94-95).

(144) Assessment of costs, effectiveness, and feasibility of annual open enrollment. In connection with the open enrollment feasibility study, review the costs, effectiveness, and administrative feasibility of an annual open enrollment period for beneficiaries who previously declined enrollment in Part D or who previously disenrolled and desire to re-enroll. See MMA § 201, proposed SSA § 201(b)(1) (p. 95).

(145) Assessment of feasibility of premium penalty for late enrollment. In connection with the open enrollment feasibility study, evaluate the possibility of a premium penalty for late enrollment, based on actuarially determined costs to the Part D program of late enrollment. See MMA § 201, proposed SSA § 201(b)(2) (p. 95).

(146) Projections concerning costs of open enrollment. In connection with the open enrollment feasibility study, make a projection of the costs to the Part D program through 2010 of an annual enrollment period. See MMA § 201, proposed SSA § 201(b)(3) (p. 95).

(147) Report on outcome of enrollment feasibility study. Prepare a report setting forth the outcome of the enrollment feasibility study, including recommendations. See MMA § 201, proposed SSA § 201(b) (flush language) (p. 95).

b. Coverage; pricing of prescription drugs.

(148) Regulation on benefit package inclusions. Promulgate a regulation setting forth which prescription drugs must be included in the benefit package. See MMA § 201, proposed SSA § 1859A(a), (b) (pp. 70-71).

(149) Regulation defining "smoking cessation agents." Promulgate a regulation setting forth which prescription drugs constitute valid and covered "smoking cessation agents." See MMA § 201, proposed SSA § 1859A(b)(1) (p. 71).

(150) Regulation governing criteria for determining exclusions from coverage. Promulgate a regulation governing general criteria for determining when a specific prescription drug will be excluded from coverage. See MMA § 201, proposed SSA § 1859A(b)(2) (p. 71).

(151) Multiple regulations setting forth specific exclusions from coverage. Promulgate a regulation governing specific exclusions from coverage. See MMA § 201, proposed SSA § 1859A(b)(2) (p. 71).

(152) Regulation setting forth certain Part D exclusions based on coverage under Parts A or B. Promulgate a regulation setting forth the specific prescription drugs that are not covered under new Part D by virtue of their coverage under Part A or B. See MMA § 201, proposed SSA § 1859A(b)(3) (pp. 71-72).

(153) Ensuring compliance with statutory deadlines governing commencement of coverage. Ensure that coverage for enrolling individuals commences in accordance with the statutory commencement of coverage deadline. See MMA

§ 201, proposed SSA § 1859C(b)(3)(B) (p. 74).

(154) Ensuring compliance with duration of coverage requirements. Ensure coverage for the full duration of the period prescribed in § 1838. See MMA § 201, proposed SSA § 1859C(e)(1) (p. 74).

(155) Regulation defining "prescription drug." Promulgate a regulations setting forth the scope of the term "prescription drug." See MMA § 201, proposed SSA § 1859J (p. 94).

c. Benefit manager contracts with HCFA; benefit manager responsibilities.

(156) Contracting with benefit managers. Enter into contracts with benefit managers for the administration of Part D benefits. See MMA § 201, proposed SSA § 1859G(a) (p. 78).

(157) Establishment of benefit manager geographic service areas. Divide the total geographic area served by Part D into at least 15 geographic service areas for purposes of benefit administration. See MMA § 201, proposed SSA § 1859G(b)(1) (p. 78).

(158) Determinations concerning competitive impact in connection with establishment of geographic service areas. In determining or adjusting the boundaries of the geographic service areas, take into consideration the level of competition that will result among contracting entities. See MMA § 201, proposed SSA § 1859G(b)(1) (p. 79).

(159) Regulation governing bidding process. Promulgate a regulation to govern the bidding process for benefit manager contracts. See MMA § 201, proposed SSA § 1859G(c)(1) (p. 79).

NOTE: As prospective benefit managers would be required to negotiate prescription drug prices with manufacturers and suppliers and, based on the results of the negotiations, develop a proposed price schedule for review and approval (or modification) by HCFA, it is likely that this regulation would include provisions governing negotiations and standards for review and approval by HCFA. See mandates 279, 286.

(160) Regulation governing benefit manager qualifications. Promulgate a regulation to govern the requirements to qualify as a benefit manager. See MMA § 201, proposed SSA § 1859G(c)(1), (2) (p. 79).

(161) Implementation of benefit manager bidding process for each geographic service area. Conduct the bidding process for the award of benefit manager contracts. See MMA § 201, proposed SSA § 1859G(c)(1)(A) (p. 79).

(162) Determinations regarding extension of benefit manager contracts on noncompetitive basis. Make determinations as to whether to extend benefit manager contracts on a noncompetitive basis (or, alternatively, to conduct competitive bidding). See MMA § 201, proposed SSA § 1859G(c)(1)(B) (p. 79).

(163) Consideration of individual entity bidding packages. For each bidding entity (candidate for benefit manager), determine whether the entity is capable of administering a prescription drug benefit program, as well as the merits of the bid in relation to other bidders (including proposed prices schedules for prescription drugs, see mandate 279). See MMA § 201, proposed SSA § 1859G(c)(2)(B) (p. 80).

(164) Assessment of bidding entities' officers, directors, and employees. In considering the capability of an entity to administer a prescription drug benefit program, assess the entity's officers, directors, agents and managing employees in terms of professional competence and professional and financial integrity. See MMA § 201, proposed SSA § 1859G(c)(2)(C) (p. 80).

(165) Assessment of bidding entities' financial resources. Determine whether the financial resources of each bidding entity are adequate to enable the entity to perform services under a contract without risk of insolvency. See MMA § 201, proposed SSA § 1859G(c)(2)(C) (p. 80).

(166) Provision of information for contract award and renewal. Promulgate a regulation setting forth the requirements for proposals for contract award or renewal. See MMA § 201, proposed SSA § 1859G(c)(3) (p. 80).

NOTE: This regulation would probably include provisions governing review and approval (or modification) by HCFA of price schedules for prescription drugs. See mandates 279, 280, 286.

(167) Evaluation and adjustment of fee and cost estimates in accordance with Federal Acquisition Regulation. In making contract award determinations, consider, on a comparative basis, the bidding entities' estimated contract costs, taking into account the entity's proposed fees and price/cost estimates. Evaluate and adjust those estimates in accordance with the Federal Acquisition Regulation governing contracting by negotiation. See MMA § 201, proposed SSA § 1859G(c)(4)(A) (p. 81).

(168) Evaluation of bidding entities' prior prescription drug program administration experience. In making contract award determinations, consider, on a comparative basis, the bidding entities' prior experience in administering a prescription drug benefit program. See MMA § 201, proposed SSA § 1859G(c)(4)(B) (p. 81).

(169) Evaluation of bidding entities' benefit management services. In making contract award determinations, consider, on a comparative basis, the quality and efficiency of the bidding entities' benefit management services with respect to such matters as claims processing and benefits coordination; recordkeeping and reporting; and drug utilization review, patient information and other activities supporting the quality of care. See MMA § 201, proposed SSA § 1859G(c)(4)(D) (p. 81).

(170) Evaluation of additional factors to be established by HCFA. In making contract award determinations, consider, on a comparative basis, additional factors as deemed necessary by HCFA to evaluate application merits. See MMA § 201, proposed SSA § 1859G(c)(4)(E) (pp. 81-82).

(171) Regulatory guidelines concerning waiver of conflict of interest rules. Establish guidelines as to when and under what circumstances it would be appropriate for HCFA to waive conflict of interest rules generally applicable to federal acquisitions. See MMA § 201, proposed SSA § 1859G(c)(5) (p. 82).

(172) Individual conflict-of-interest waiver determinations. Make individual conflict-of-interest waiver determinations, taking into account consistency of waiver with program purposes and enrollee best interests, promotion of competition and efficiency, and promotion of program objectives. See MMA § 201, proposed SSA § 1859G(c)(5) (p. 82).

(173) Regulatory guidelines concerning maximization of competition. Develop guidelines for maximizing competition in the awarding of contracts under Part D, taking into account the need to maintain sufficient numbers of entities eligible and willing to administer benefits and to ensure vigorous competition for contracts. See MMA § 201, proposed SSA § 1859G(c)(6) (p. 82).

(174) Regulation governing functions of benefit managers. Promulgate a regulation setting forth the specific functions for which benefit managers will be responsible. See MMA § 201, proposed SSA § 1859G(d) (p. 82).

(175) Regulation establishing additional benefit manager obligations. Promulgate a regulation establishing additional requirements for benefit managers. See MMA § 201, proposed SSA § 1859G(d)(9) (p. 86).

(176) Work load transfer upon termination of benefit manager contracts. Transfer work load to alternative benefit managers during the phase out period of a terminated benefit manager. See MMA § 201, proposed SSA § 1859G(h) (p. 89).

(177) Compliance monitoring of benefit manager performance. Monitor the compliance of benefit managers with their contracts and applicable regulations, including the investigation of complaints. See MMA § 201, proposed SSA § 1859G(a) (p. 78).

(178) Administrative review with respect to benefit managers. Conduct administrative proceedings in connection with enforcement against noncomplying benefit managers, as well as to resolve benefit manager grievances against HCFA. See MMA § 201, proposed SSA § 1859G(a) (p. 78).

d. Pharmacy contracts with benefit managers; pharmacy responsibilities.

(179) Regulation governing pharmacy participation requirements. Promulgate a regulation setting forth the requirements for pharmacy participation. See MMA § 201, proposed SSA § 1859G(e)(1) (p. 86).

(180) Regulation governing pharmacies' quality of services. Promulgate a regulation to govern the quality of services to be provided by pharmacies under Part D. See MMA § 201, proposed SSA § 1859G(e)(2)(B) (p. 87).

(181) Regulation governing pharmacies' adequacy of access. Promulgate a regulation to govern adequacy of access to services to be provided by pharmacies under Part D. See MMA § 201, proposed SSA § 1859G(e)(2)(B) (p. 87).

e. Pricing of premiums; collection of premiums.

(182) Determination and promulgation of annual premium rates. Determine and promulgate annually a monthly premium rate for the following year. See MMA § 201, proposed SSA § 1859D(a)(1) (pp. 74-75).

(183) Establishment of annual premiums for each enrollee. Establish annually the premiums to be paid by each enrollee (*i.e.*, a separate premium for each plan). See MMA § 201, proposed SSA § 1859D(a)(2)(B) (p. 75).

(184) Publication of actuarial assumptions used in establishing premium amounts. Publish annually, simultaneously with promulgation of the premium rates for the succeeding year, a statement setting forth the actuarial assumptions and bases employed in arriving at the premium amounts and rates. See MMA § 201, proposed SSA § 1859D(a)(3) (p. 76).

(185) Identification of premium deficiencies from individuals enrolled in Social Security. Identify individuals whose Social Security payments are insufficient to cover such individuals' Part D premiums, as well as the specific amount of insufficiency for each individual. See MMA § 201, proposed SSA § 1859D(b)(2)(A) (p. 77).

(186) Collection of premiums from individuals whose SSA checks are insufficient. Collect monthly premium payments from individuals when the amount to be paid by the Social Security Administration is insufficient to cover the amount of such individuals' premium payments. See MMA § 201, proposed SSA § 1859D(b)(2)(A) (p. 77).

(187) Regulation governing assessment of premiums from certain Part A and B enrollees. Promulgate a regulation to govern the procedure for assessing premiums from Part A and Part B enrollees whose Social Security checks are insufficient to cover premiums under Parts A/B and Part D. See MMA § 201, proposed SSA § 1859D(b)(2)(B) (p. 77).

(188) Regulation governing assessment of premiums from federal government retirees whose benefit checks are insufficient. Promulgate a regulation to govern the procedure for assessing premiums from federal government retirees whose benefit checks are insufficient to cover monthly premium amounts. See MMA § 201, proposed SSA § 1859D(b)(2)(B) (p. 77).

(189) Transfers of funds representing direct premium payments from Part A, Part B, and Railroad Retirement beneficiaries. Deposit premium payments received directly from enrollees with the Treasury Department to the credit of the Prescription Drug Insurance Account. See MMA § 201, proposed SSA § 1859D(b)(2)(C) (p. 77).

(190) Regulation governing the non-institution of benefit price structures. Develop guidelines to ensure that HCFA does not "institute a price structure for benefits" while at the same time approving the pricing of benefit packages pursuant to § 101(a)(4), (b)1) (compare mandates 3, 9). See MMA § 201, proposed SSA § 1859G(i) (p. 89).

NOTE: There is a tension between this requirement and the requirement that HCFA approve price lists for all benefit managers. See mandate 279.

f. Reimbursements; funding of program.

(191) Transfer of funds from Prescription Drug Insurance Account. Make payments from the Prescription Drug Insurance Account within the Supplementary Medical Insurance Trust Fund representing 50% (or more, under certain circumstances, see mandate 192) of the negotiated price for each such covered prescription drug. See MMA § 201, proposed SSA § 1859B(a) (p. 72).

NOTE: The bill does not specify to whom the payments are to be made. It is unclear whether HCFA would be responsible for reimbursing individual Part D enrollees directly, or whether lump sum payments would be made to benefit managers, who would then make individual payments. (The answer to this question affects the distribution of mandates between HCFA and the benefit managers. We assume here that HCFA will make the payments directly to the enrollees.)

(192) Determinations as to whether to reimburse in excess of 50% of negotiated prices. Determine whether to reimburse for more than 50% of the negotiated price for prescription drug usage, taking into account: (i) proposals of benefit managers; and (ii) whether doing so would increase aggregate costs to the Insurance Account. See MMA § 201, proposed SSA § 1859B(a) (p. 72).

(193) Adjustments to prescription drug benefit limit. For years subsequent to 2009, adjust the prescription drug benefit limit to take into account percentage changes in the consumer price index. See MMA § 201, proposed SSA § 1859B(b)(2) (p. 73).

(194) Calculation of annual nationwide total benefit estimate. Calculate an annual estimate for the following year of the total of the benefits that will be payable from the Prescription Drug Insurance Account for prescription drugs dispensed with respect to Part D enrollees. See MMA § 201, proposed SSA § 1859D(a)(2)(A) (p.75).

(195) Establishment of annual contingency margin. In calculating an annual estimate of benefits payable, establish an appropriate contingency margin. See MMA § 201, proposed SSA § 1859D(a)(2)(A) (p. 75).

(196) Certifications concerning payments from Prescription Drug Insurance Account. Certify to the managing trustee of the Federal Supplemental Medicare Insurance Trust Fund amounts to be paid for Part D reimbursements and administrative expenses. See MMA § 201, proposed SSA § 1859F(b) (p. 78).

(197) Regulation governing alternative coinsurance. Promulgate a regulation setting forth objective criteria for consideration of benefit managers' proposals for alternative coinsurance (*i.e.*, increased government cost sharing for generic prescription drugs, formulary prescription drugs, or mail-order prescription drugs, based on evidence that such increased cost sharing would not result in an increase in the aggregate costs to the Prescription Drug Insurance Account). See MMA § 201, proposed SSA § 1859G(d)(8) (p. 86).

(198) Determinations on benefit managers' proposals for alternative coinsurance. Consider specific applications or proposals of benefit managers for alternative coinsurance. See MMA § 201, proposed SSA § 1859G(d)(8) (p. 86).

(199) Regulation governing bonus and penalty incentives. Develop bonus and penalty incentives to encourage administrative efficiency for inclusion in HCFA-benefit manager contracts. See MMA § 201, proposed SSA § 1859G(g)(1) (p. 88).

(200) Regulation governing incentives based on sharing of savings realized. Develop incentives under which benefit managers would share in any benefit savings achieved for inclusion in HCFA-benefit manager contracts. See MMA § 201, proposed SSA § 1859G(g)(2) (p. 88).

(201) Regulation governing risk sharing arrangements. Develop risk sharing arrangements related to benefit payments for inclusion in contracts with benefit managers. See MMA § 201, proposed SSA § 1859G(g)(3) (p. 88).

(202) Negotiations with benefit managers for special risk sharing arrangements. Negotiate specific risk sharing arrangements with specific benefit managers, and incorporate such arrangements into the HCFA-benefit manager contracts. See MMA § 201, proposed SSA § 1859G(g)(3) (p. 88).

(203) Regulation setting forth other benefit manager incentives. Develop other incentives for inclusion in HCFA-benefit manager contracts to the extent that such incentives would likely be effective in managing costs or utilization. See MMA § 201, proposed SSA § 1859G(g)(4) (p. 88).

g. Grievances; dispute resolution.

(204) Regulation governing grievance and appeals procedures. Promulgate a regulation to govern the grievance and appeals procedures to be established by benefit managers to resolve complaints against benefit managers and participating pharmacies. See MMA § 201, proposed SSA § 1859G(d)(6)(B) (p. 85).

h. Education.

(205) Regulation governing benefit managers' educational programs. Promulgate a regulation setting forth the minimum requirements of the educational and informational programs to be established and implemented by benefit managers. See MMA § 201, proposed SSA § 1859G(d)(5) (p. 85).

i. Confidentiality.

(206) Regulation governing confidentiality requirements. Promulgate a regulation setting forth confidentiality standards to be maintained by benefit managers, taking into account the requirements of 5 U.S.C. §§ 552a and 1106, as well as additional requirements necessitated by the nature of the Part D benefit program. See MMA § 201, proposed SSA § 1859G(d)(6)(A) (p. 85).

j. Access.

(207) Regulation governing coordination of benefits within home service area. Promulgate a regulation setting forth general requirements for the coordination of benefits among HCFA, benefit managers, pharmacies, and other relevant entities. See MMA § 201, proposed SSA § 1859G(d)(3)(B) (p. 84).

(208) Regulation governing coordination of benefits outside home service area. Promulgate a regulation to govern the coordination of benefits among HCFA, benefit managers, pharmacies, and other relevant entities when enrollees are outside the home service area. See MMA § 201, proposed SSA § 1859G(d)(3)(B) (p. 84).

(209) Implementation of coordination of benefit requirements in conjunction with benefit managers, pharmacies, and other entities. Coordinate with benefit managers, pharmacies, and other relevant entities as necessary to ensure the appropriate coordination of benefits to enrollees. See MMA § 201, proposed SSA § 1859G(d)(3)(B) (p. 84).

(210) Implementation of special outside-the-service-area coordination of benefit requirements. Coordinate with benefit managers, pharmacies, and other relevant entities to ensure that an individual enrollee has access to his or her in-service area coverage when traveling outside the home service area. See MMA § 201, proposed SSA § 1859G(d)(3)(B) (p. 84).

(211) Regulation governing pharmacy participation and pharmacy networks. Promulgate a regulation to govern the participation rights of eligible pharmacies and the adequacy of pharmacy networks. See MMA § 201, proposed SSA § 1859G(d)(1)(B) (p. 83).

k. Cost containment.

(212) Evaluation of bidding entities' effectiveness in containing costs. In making contract award determinations, consider, on a comparative basis, bidding entities' effectiveness in containing costs through pricing incentives and utilization management. See MMA § 201, proposed SSA § 1859G(c)(4)(C) (p. 81).

(213) Regulation governing cost containment. Promulgate a regulation to govern the cost containment strategies of benefit managers and pharmacies. See MMA § 201, proposed SSA § 1859G(c)(4)(C), (e)(2)(B) (p. 81, 87-88).

l. Quality assurance; error reduction.

(214) Regulation governing prescription drug error reduction and quality assurance programs. Promulgate a regulation governing the parameters of prescription drug error reduction and quality assurance programs to be developed and implemented by benefit managers and pharmacies. See MMA § 201, proposed SSA § 1859G(c)(3)(C) (p. 80).

m. Utilization.

(215) Regulation governing prescription drug utilization programs. Promulgate a regulation governing the parameters of prescription drug utilization programs to be developed and implemented by benefit managers. See MMA § 201, proposed SSA §

1859G(c)(3)(C) (p. 80).

(216) Assessment and modification of specific benefit managers' cost and utilization review programs. Periodically reassess and determine whether to modify specific benefit managers' utilization review programs, especially in light of new medical and pharmaceutical developments. See MMA § 201, proposed SSA § 1859G(d)(4)(A) (p. 84).

(217) Promulgation of reporting requirements. Prescribe requirements for the reporting of financial and utilization data by benefit managers, taking into account standard commercial practices. See MMA § 201, proposed SSA § 1859G(d)(7)(B) (p. 86).

n. Control of fraud, abuse, and waste.

(218) Regulation governing benefit managers' programs to control fraud, abuse, and waste. Promulgate a regulation governing the parameters of programs to be established by benefit managers to control fraud, abuse, and waste. See MMA § 201, proposed SSA § 1859G(d)(4)(B) (p. 85).

o. Employer plans.

(219) Establishment of Employer Incentive Program. Develop a program, to be known as the "Employer Incentive Program," that will encourage employers and other sponsors of employment-based health care coverage to provide adequate prescription drug benefits to retirees by partially subsidizing sponsors' costs of coverage for qualified plans. See MMA § 201, proposed SSA § 1859H(a) (p. 89).

(220) Annual attestation and assurances in connection with Employer Incentive Program. Promulgate a regulation setting forth the attestations and assurances to be provided by employer sponsors in order to participate in the Employer Incentive Program. See MMA § 201, proposed SSA § 1859H(b)(1) (p. 90).

(221) Audits of sponsors and employment-based retiree health plans. Audit the records of sponsors and employment-based retiree health coverage plans to ensure the adequacy of prescription drug coverage, the accuracy of payments made, and such other matters as may be appropriate. See MMA § 201, proposed SSA § 1859H(b)(3), (d) (pp. 90, 91).

(222) Additional reporting requirements in connection with Employer Incentive Program. Promulgate a regulation establishing additional requirements deemed necessary to administer the Employer Incentive Program. See MMA § 201, proposed SSA §

1859H(b)(4) (p. 90).

(223) Calculation of incentive payment amounts. Calculate incentive payment amounts for each sponsor on a quarterly basis. See MMA § 201, proposed SSA § 1859H(c)(1), (2) (p. 91).

(224) Processing of incentive payments. Process incentive payments to sponsors (or, at the sponsor's direction, to the appropriate employment-based health plan) on a quarterly basis. See MMA § 201, proposed SSA § 1859H(c)(1) (p. 91).

(225) Administrative enforcement in connection with Employer Incentive Program. Conduct enforcement proceedings and impose penalties on sponsors or employment-based health plans based on audit results. See MMA § 201, proposed SSA § 1859H(d) (p. 91).

(226) Regulation governing enrollment of retirees upon termination of employer-sponsored coverage. Promulgate a regulation to govern the enrollment in Part D of retirees whose employer-sponsored coverage is discontinued (or when the value of prescription drug coverage offered by the employer-sponsored plan becomes less than the value of coverage under Part D). See MMA § 201, proposed SSA § 1859H(e) (p. 92).

(227) Enrollment of retirees upon termination of employer-sponsored coverage. Process the enrollment in Part D of retirees whose employer-sponsored coverage is discontinued (or when the value of prescription drug coverage offered by the employer-sponsored plan becomes less than the value of coverage under Part D). See MMA § 201, proposed SSA § 1859H(e) (p. 92).

(228) Regulation prohibiting coverage restrictions. Promulgate a regulation prohibiting the denial, limitation, or conditioning of coverage based on age or health status. See MMA § 201, proposed SSA § 1859H(f)(1), (3) (p. 93).

p. Low-income buy-in.

(229) Provision of Medicaid matching funds for Part D coverage. Provide federal matching funds for state payments made pursuant to the Medicaid buy-in of Medicare prescription drug coverage. See MMA § 202(c)(3), proposed SSA § 1903(a) (p. 102).

(230) Agreements with states for Part D enrollment of QMBs and QMDBs. Enter into agreements with states under which QMBs and QMDBs are to be enrolled in Part D. See MMA § 202(e), proposed SSA § 1859E(a) (pp. 103-04).

(231) Enrollment in Part D of former Medicaid beneficiaries. Provide an opportunity for enrollment in Part D to individuals who lose Medicaid coverage. See MMA § 202(e), proposed SSA § 1859E(b) (pp. 104-05).

q. Oversight and compliance.

(232) Additional recordkeeping and reporting requirements. Promulgate additional recordkeeping and reporting requirements as deemed necessary in implementing Part D. Undertake comprehensive oversight, compliance and enforcement with respect to all benefit manager and pharmacy activities under Part D. See MMA § 201, proposed SSA § 1859G(c)(3)(G) (p. 81).

11. Prevention Information Campaign.

(233) Preventive health care information campaign. Conduct, during 2002 and 2003, a nationwide information campaign, in collaboration with the Social Security Administration, State health insurance assistance programs, area agencies on aging, and the private sector, designed to educate Americans over age 50 and individuals with disabilities about the importance of preventive health care. See MMA § 222(a)(1) (p. 108).

(234) Distribution of comprehensive information package. Conduct, during 2002 and 2003, activities designed to encourage Medicare beneficiaries to use Medicare preventive benefits, including distribution of comprehensive information on Medicare preventive benefits to Medicare beneficiaries. See MMA § 222(a)(2) (p. 108).

(235) "Health status assessment tool." Develop and test a "health status assessment tool" with "follow-up interventions" to assist Medicare beneficiaries and their providers in identifying and mitigating health risks. See MMA § 222(a)(3) (p. 108).

(236) Nationwide education campaign to prevent falls. Conduct, during 2002 and 2003, a nationwide education and awareness campaign designed to educate older Americans on adjustments to behavior and the home environment that can prevent falls. See MMA § 222(a)(4) (p. 108).

12. Smoking Cessation Demonstration.

(237) Planning of smoking cessation demonstration project. Determine the manner of the design, implementation, and evaluation of the demonstration project. See MMA § 223(b)(1) (p. 109).

(238) Services to be included in smoking cessation demonstration project. Determine which services to include in the demonstration project, including possibly initial patient assessment, counseling, pharmacotherapy, and other services. See MMA § 223(b)(2) (p. 109).

(239) Identification of eligible individuals for participation in smoking cessation demonstration project. Determine which individuals or entities are to provide services in connection with the demonstration project, including Medicare providers, health educators, and other professionals to be designated by HCFA. See MMA § 223(b)(2) (p. 109).

(240) Reimbursement of participants in smoking cessation demonstration project. Make payments to persons furnishing health care items and services in connection with the smoking cessation demonstration project from Medicare trust funds. See MMA § 223(c)(2) (p. 110).

(241) Establishment of fee schedule for items and services provided in smoking cessation demonstration project. Develop a fee schedule for health care items and services provided in connection with the smoking cessation demonstration project. See MMA § 223(c)(2) (p. 110).

(242) Waiver of requirements in connection with smoking cessation demonstration project. Determine the extent to which otherwise applicable requirements of the Medicare program should be waived in connection with the smoking cessation demonstration project. See MMA § 223(d) (p. 110).

(243) Transfer of funds to finance smoking cessation demonstration project. Provide for the transfer from the Federal Health Insurance and Federal Supplementary Insurance Trust Fund of funds necessary to implement the smoking cessation demonstration project. See MMA § 223(e) (p. 110).

(244) Evaluation of smoking cessation demonstration project. Conduct, or cause to be conducted, an evaluation of the smoking cessation demonstration project. See MMA § 223(f) (pp. 110-11).

(245) Report to Congress on smoking cessation demonstration project. Prepare and submit to Congress a report assessing the smoking cessation demonstration project in terms of patient outcomes, cost-effectiveness of the demonstration, and quality of services furnished in the demonstration, as well as a recommendation for the continuation and expansion of the demonstration project. See MMA § 223(f) (pp. 110-11).

13. Medigap Updating and Expansion.

(246) Periodic review of "Plan K" and other Medigap options. Periodically review, in consultation with the NAIC, the standard Medigap plans to determine whether changes in the content, number, or other aspects of the plans are needed. See MMA § 233(a)(2), proposed SSA § 1882(p)(1)(F) (pp. 114-15).

(247) Development of informational materials on "Plan K" and other Medigap options. Develop informational materials on "Plan K" (in comparison with other Medigap plan options) for dissemination to Medigap beneficiaries. See MMA § 233(b), proposed SSA § 1882(e)(4) (p. 115).

(248) Provision of information to beneficiaries on "Plan K" and other Medigap options. Provide Medigap beneficiaries and prospective beneficiaries information to be used in comparing Medigap plan options. See MMA § 233(b), proposed SSA § 1882(e)(4) (p. 115).

14. Medigap Access.

(249) Regulation governing expansion of Medigap open enrollment opportunities. Promulgate a regulation governing the expansion of Medigap open enrollment opportunities, including open enrollment to disabled and end-stage renal disease Medicare beneficiaries; six-month open enrollment without medical underwriting to first-time enrollees in Part B regardless of age; an additional six-month open enrollment period for disabled or renal disease Part B enrollees who turn 65; and a special six-month open enrollment period for disabled or renal disease Part B enrollees who are under 65. See MMA § 235(a)(1), proposed SSA § 1882(s) (pp. 117-18).

(250) Development of Medigap rating standards for non-elderly beneficiaries. Request that NAIC develop rating standards for Medigap policies for individuals who are under age 65. See MMA § 235(a)(3), proposed SSA § 1882(s) (pp. 118-19).

15. Reporting to Congress on Policy Options for Improving Medicare.

(251) Report to Congress on Medicare supplemental coverage options. Prepare and transmit to Congress before January 1, 2002, a detailed report on policy options for improving Medicare supplemental coverage, with particular attention to limiting out-of-pocket costs for health care items and services. See MMA § 223(a) (p. 116).

(252) Assessment of impact of multiple sources of coverage on Medicare supplemental insurance program. In preparing the report to Congress, consider the effects of beneficiaries having multiple sources of health care coverage (including duplication of coverage and incentives for over-utilization of services). See MMA § 223(b)(1) (p. 116).

(253) Assessment and comparison of Medicare and private sector cost sharing. In preparing the report to Congress, compare total cost sharing by Medicare beneficiaries (under Medicare and Medicare supplemental policies) with cost sharing by enrollees in private sector health insurance. See MMA § 223(b)(2) (p. 116).

(254) Assessment of information dissemination improvements. In preparing the report to Congress, consider means of improving beneficiary information on the comparative cost and quality of Medicare supplemental policies. See MMA § 223(b)(3) (p. 116).

(255) Assessment of options for restructuring Medicare supplemental insurance program. In preparing the report to Congress, consider options for restructuring, and the feasibility and advisability (including the potential for reducing beneficiaries' out-of-pocket costs and unnecessary utilization) of alternatives, including: (a) optional unsubsidized supplemental coverage under Medicare requiring beneficiary cost sharing; and (b) a Medicare supplemental benefit requiring beneficiary copayments (to be offered by private entities as a supplement to coverage under original Medicare as part of the competitive defined benefit). See MMA § 223(b)(4) (pp. 116-17).

B. Mandates Imposed on the Social Security Administration.

1. Prescription Drug Benefit Program.

a. Pricing of premiums; collection of premiums.

(256) Collection of premiums. Collect premium amounts from individual enrollees through deductions from Social Security and Railroad Retirement Act benefit checks. See MMA § 201, proposed SSA § 1859D(b)(1)(A) (cross-referencing 42 U.S.C. § 1840(a), (b), (d)) (p. 76).

2. Prevention Information Campaign.

(257) Preventive health care information campaign. Collaborate with HCFA in conducting, during 2002 and 2003, a nationwide information campaign designed to educate Americans over age 50 and individuals with disabilities about the importance of preventive health care. See MMA § 222(a)(1) (p. 108).

C. Mandates Imposed on the Office of Personnel Management.

1. Prescription Drug Benefit Program.

a. Pricing of premiums; collection of premiums.

(258) Collection of premiums. Collect premium amounts from individual enrollees through deductions federal employee retirement benefit checks. See MMA § 201, proposed SSA § 1859D(b)(1)(A) (cross-referencing 42 U.S.C. § 1840(a), (b), (d)) (p. 76).

(259) Collection of premiums from federal government retirees. Collect monthly premium payments from retired federal government employees whose monthly benefit checks are insufficient to cover the Part D monthly premium amount. See MMA § 201, proposed SSA § 1859D(b)(2)(B) (p. 77).

NOTE: The agency responsible for collection will be determined pursuant to the regulation to be promulgated by HCFA (see mandate 188). This agency would most likely be OPM.

(260) Transfers of funds representing direct premium payments from federal employment retirees. Deposit premium payments received directly from enrollees with the Treasury Department to the credit of the Prescription Drug Insurance Account. See MMA § 201, proposed SSA § 1859D(b)(2)(C) (p. 77).

D. Mandates Imposed on the Treasury Department.

1. Prescription Drug Benefit Program.

a. Pricing of premiums; collection of premiums.

(261) Transfers of funds collected by SSA and OPM. Transfer to the Prescription Drug Insurance Fund premium amounts collected by the Social Security Administration and the Office of Personnel Management on a quarterly basis. See MMA § 201, proposed SSA § 1859D(b)(1)(B) (p. 76).

(262) Establishment of Prescription Drug Insurance Account. Establish a "Prescription Drug Insurance Account" within the Federal Supplemental Medical Insurance Trust Fund. See MMA § 201, proposed SSA §§ 1859B(a), 1859F(a) (pp. 72, 77-78).

(263) Maintenance of funds in Prescription Drug Insurance Account. Ensure that funds deposited in the Prescription Drug Insurance Account are kept separate from all other funds within the Federal Supplemental Medicare Insurance Trust Fund. See MMA § 201, proposed SSA § 1859F(a) (p. 78).

b. Reimbursements; funding of program.

(264) Payments from Prescription Drug Insurance Account. Pay from time to time from the Prescription Drug Insurance Account such amounts as HHS certifies are necessary to make benefit/reimbursement payments under Part D, as well as payments for administrative expenses in connection with Part D. See MMA § 201, proposed SSA § 1859F(b) (p. 78).

E. Mandates Imposed on Congress.

1. Prescription Drug Benefit Program.

a. Reimbursements; funding of program.

(265) Appropriations for Part D program. Appropriate, from time to time, Treasury funds not otherwise appropriated to the Prescription Drug Insurance Account to cover the provision of benefits under Part D. See MMA § 201, proposed SSA § 1859I (p. 94).

b. Employer plans.

(266) Appropriations for Employer Incentive Program. Appropriate, from time to time, Treasury funds not otherwise appropriated for the payment of incentive amounts under the Employer Incentive Program. See MMA § 201, proposed SSA § 1859H(g) (p. 94).

c. Low-income buy-in.

(267) Appropriations of Medicaid matching funds for Part D coverage. Appropriate federal matching funds for state payments to be made pursuant to the Medicaid buy-in of Medicare prescription drug coverage. See MMA § 202(c)(3), proposed SSA § 1903(a) (p. 102).

F. Mandates Imposed on the National Association of Insurance Commissioners.

1. Medigap Updating and Expansion.

(268) Creation of new Medigap "Plan K" option. Create a new Medigap plan option to be known as "Plan K," under which the beneficiary would make nominal payments and all or a portion of the Part B deductible. See MMA § 233(a)(1)(A), proposed SSA § 1882(p)(1)(E) (p. 113).

(269) Periodic review of "Plan K" and other Medigap options. Assist HCFA in its periodic review of the standard Medigap plans to determine whether changes in the content, number, or other aspects of the plans are needed. See MMA § 233(a)(2)(A), proposed SSA § 1882(p)(1)(F) (pp. 114-15).

(270) Periodic amendments to terms of "Plan K" and other Medigap plans. Develop and implement changes in the standard Medigap plans, as deemed necessary based on periodic review with HCFA. See MMA § 233(a)(2)(B), proposed SSA § 1882(p)(1)(F) (p. 115).

2. Medigap Access.

(271) Development of Medigap rating standards for non-elderly beneficiaries. Assist HCFA in the development of rating standards for Medigap policies for individuals who are under age 65. See MMA § 235(a)(3), proposed SSA § 1882(s) (pp. 118-19).

(272) Publication of Medigap rating standards for non-elderly beneficiaries. Publish the rating standards for Medigap policies for individuals who are under age 65. See MMA § 235(a)(3), proposed SSA § 1882(s) (pp. 118-19).

G. Mandates Imposed on States.

1. Prescription Drug Benefit Program.

a. Low-income buy-in.

(273) Price limitation with respect to prescription drugs purchased by states. Incorporate into state plans a provision that, in the case of any individual who is dually eligible for Medicare and Medicaid, and for whom the state elects to pay Part D premiums, the state will purchase all prescription drugs for such individual without regard for whether the benefit limit for the individual under Part D has been reached. See MMA § 202(a)(2), proposed SSA § 1902(a)(66) (p. 99).

(274) Payment of Part D premiums and coinsurance for QMBs. Pay Part D premiums and coinsurance for "qualified Medicare beneficiaries" ("QMBs") (*i.e.*, individuals with incomes below 100% of the poverty line) until the annual Part D benefit is reached. See MMA § 202(b), proposed SSA § 1905(p) (pp. 99-100).

(275) Payment of Part D premiums and coinsurance for QMDBs between 100% and 135% of poverty line. Pay Part D premiums and coinsurance for "qualified Medicare drug beneficiaries" ("QMDBs") with incomes between 100% and 135% of the poverty line until the annual Part D benefit is reached. See MMA § 202(c), proposed SSA § 1905(v) (pp. 100-01).

(276) Payment of Part D premiums and coinsurance for QMDBs between 135% and 150% of poverty line. Pay Part D premiums and coinsurance for "qualified Medicare drug beneficiaries" ("QMDBs") with incomes between 135% and 150% of the poverty line based on a linear sliding scale ranging from 100% to zero. See MMA § 202(c), proposed SSA § 1905(v) (pp. 100-01).

(277) Agreements with HCFA for Part D enrollment of QMBs and QMDBs. Enter into agreements with HHS under which QMBs and QMDBs are to be enrolled in Part D. See MMA § 202(e), proposed SSA § 1859E(a) (p. 103).

2. Prevention Information Campaign.

(278) Preventive health care information campaign. Collaborate with HCFA in conducting, during 2002 and 2003, a nationwide information campaign designed to educate Americans over age 50 and individuals with disabilities about the importance of preventive health care. See MMA § 222(a)(1) (p. 108).

H. Mandates Imposed on Benefit Managers.

1. Prescription Drug Benefit Program.

a. Coverage; pricing of prescription drugs.

(279) Development of prescription drug price schedule. Develop a prescription drug price schedule, including annual price increases and differentials between formulary and non-formulary prices, for inclusion in the bidding package to be approved by HCFA as a condition for becoming a benefit manager. See MMA § 201, proposed SSA §1859G(c)(3)(B) ("[a]n entity's proposal for award or renewal of a contract under this section shall...include a proposal for the prices of drugs and annual increases in such prices, including differentials between formulary and non-formulary prices...") (p. 80); and §1859(d)(1)(A) (pp. 82-83).

NOTE: The prescription drug prices schedule must be included in the bidding package, and hence must be reviewed by HCFA. See mandate 163.

(280) Periodic renegotiation and revisions of prescription prices. Ensure that the list of negotiated prices for specific prescription drugs is regularly updated and readily available in the service area to health care professionals, participating pharmacies, and enrollees. See MMA § 201, proposed SSA § 1859G(d)(1)(C) (p. 83).

NOTE: This language makes clear that upon renegotiation HCFA would have to reapprove (or modify) the bidding manager's price schedule as a condition of renewal.

b. Benefit manager contracts with HCFA; benefit manager responsibilities.

(281) Contracting with HCFA. Enter into contracts with HCFA for the administration of Part D benefits. See MMA § 201, proposed SSA § 1859G(a) (p. 78).

(282) Preparation of bidding package. Prepare a bid package demonstrating that the entity is capable of administering a prescription drug benefit program, including that the entity has sufficient expertise, personnel and resources to perform effectively the benefit administration functions for the relevant geographic service area or areas. See MMA § 201, proposed SSA § 1859G(c)(2)(B) (p. 80).

(283) Provision of information establishing qualifications of bidding entity's officers, directors, and employees. Demonstrate to HCFA that the entity's officers, directors, agents and managing employees possess adequate professional competence and professional and financial integrity. See MMA § 201, proposed SSA § 1859G(c)(2)(C) (p. 80).

(284) Establishment of bidding entity's financial resources. Demonstrate to HCFA that the entity's financial resources are adequate to enable the entity to perform services under a contract without risk of insolvency. See MMA § 201, proposed SSA § 1859G(c)(2)(C) (p. 80).

(285) Preparation of proposals for contract renewal. Prepare a proposal for contract renewal with HCFA to administer the prescription drug benefit program for the relevant geographic area or areas. See MMA § 201, proposed SSA § 1859G(c) (p. 80).

(286) Price negotiations for specific prescription drugs. Negotiate prices for specific prescription drugs with manufacturers, wholesalers and pharmacies. See MMA § 201, proposed SSA § 1859G(d)(1)(A) (pp. 82-83).

NOTE: The results of price negotiations would have to be embodied in a price schedule, which in turn would have to be reviewed and approved by HCFA as a condition of obtaining a contract to serve as a benefit manager. See mandates 163, 279.

(287) Development of administrative costs proposal. Develop a cost proposal setting forth the entity's proposed charges for administration of the prescription drug program. See MMA § 201, proposed SSA § 1859G(c)(3)(A) ("[a]n entity's proposal for award or renewal of a contract under this section [1859G(c)(3)] shall...include a cost proposal setting forth the entity's proposed charges for administration of the prescription drug benefit") (p. 80).

(288) Reporting requirement with respect to past performance. Provide HCFA with information about the entity's past performance, as directed by HCFA. See MMA § 201, proposed SSA § 1859G(c)(3)(D), (4)(B) (pp. 80, 81).

(289) Reporting requirement with respect to ownership and affiliate interests. Provide HCFA with information about the entity's ownership and/or shared financial interests with other entities involved in the delivery of the prescription drug benefit. See MMA § 201, proposed SSA § 1859G(c)(3)(E) (pp. 80-81).

(290) Additional recordkeeping and reporting requirements. Obtain, and report to HCFA, other information and materials as required by HCFA. See MMA § 201, proposed SSA § 1859G(c)(3)(G) (p. 81).

(291) Provision of information concerning benefit management services. Gather, prepare, and provide to HCFA information on the quality and efficiency of the bidding entity's benefit management services with respect to such matters as claims processing and benefits coordination; recordkeeping and reporting; and drug utilization review, patient information and other activities supporting the quality of care. See MMA § 201, proposed SSA § 1859G(c)(4)(D) (p. 81).

(292) Provision of information concerning benefit management services. Gather, prepare, and provide to HCFA information on such additional factors as HCFA deems necessary to evaluate the application on the merits. See MMA § 201, proposed SSA § 1859G(c)(4)(E) (pp. 81-82).

(293) Recordkeeping with respect to enrollees. Maintain accurate, updated records of all enrolled individuals residing in the service area (other than Part C enrollees). See MMA § 201, proposed SSA § 1859G(d)(2) (p. 83).

(294) Compliance with additional requirements imposed by HCFA. Comply with additional requirements to be imposed by regulation by HCFA. See MMA § 201, proposed SSA § 1859G(d)(9) (p. 86).

(295) Ensuring compliance with state and local licensing requirements. Ensure that participating pharmacies maintain compliance with all applicable state and local licensing requirements. See MMA § 201, proposed SSA § 1859G(e)(2)(A) (pp. 86-87).

(296) Compliance monitoring by HCFA. Cooperate with requests of HCFA in connection with HCFA's monitoring of the benefit manager's compliance with its contract with HCFA. See MMA § 201, proposed SSA § 1859G(a) (p. 78).

(297) Administrative review by HCFA. Participate, as both complainant and respondent, in HCFA administrative proceedings in connection with enforcement for alleged noncompliance and resolution of benefit manager grievances against HCFA. See MMA § 201, proposed SSA § 1859G(a) (p. 78).

c. Pharmacy contracts with benefit managers; pharmacy responsibilities.

(298) Contracting with pharmacies. Enter into participation agreements with qualifying pharmacies. See MMA § 201, proposed SSA § 1859G(d)(1)(B), (e)(1) (pp. 83, 86).

(299) Periodic updating of participating pharmacies list. Ensure that the list of pharmacies with participation agreements with the benefit manager is regularly updated and readily available in the service area to health care professionals, participating pharmacies, and enrollees. See MMA § 201, proposed SSA § 1859G(d)(1)(C) (p. 83).

(300) Monitoring of pharmacy compliance. Monitor on an ongoing basis the compliance of participating pharmacies with the regulations to be promulgated by HCFA governing quality of services and adequacy of access. See MMA § 201, proposed SSA § 1859G(e)(2)(B) (p. 87).

d. Reimbursements; funding of program.

(301) Determinations regarding the necessity of reimbursements in excess of 50% of negotiated prices. Determine, pursuant to § 1859G(d)(8), whether to propose to HCFA/HHS that more than 50% of the negotiated price for prescription drug usage be reimbursed in specific instances. Make specific proposals to HCFA. See MMA § 201, proposed SSA § 1859B(a) (p. 72).

(302) Processing of claims. Administer enrollee claims for payment of benefits under Part D. See MMA § 201, proposed SSA § 1859G(d)(3)(A) (p. 83).

(303) Determination of claim payment amounts. Determine the amounts of specific benefit payments to be made under Part D. See MMA § 201, proposed SSA § 1859G(d)(3)(A) (pp. 83-84).

(304) Processing of funds. Receive, disburse, and account for funds used in making specific benefit payments under Part D. See MMA § 201, proposed SSA § 1859G(d)(3)(A) (p. 84).

(305) Transmittal of explanation of benefits to each enrollee. Furnish to each enrollee an explanation of benefits that (i) lists the items and services for which payments have been made; and (ii) includes a notice of the enrollee's right to request an itemized statement. See MMA § 201, proposed SSA § 1859G(d)(3)(C) (p. 84).

NOTE: Items (i) and (ii) appear contradictory, but this is the language in cross referenced SSA § 1806(a).

(306) Monthly enrollee notices setting forth remaining balances. Furnish each enrollee, once per month, a notice of the balance of benefits remaining for the current year. See MMA § 201, proposed SSA § 1859G(d)(3)(C) (p. 84).

(307) Proposals for alternative coinsurance. Prepare proposals for alternative coinsurance (*i.e.*, increased government cost sharing for generic prescription drugs, formulary prescription drugs, or mail-order prescription drugs, based on evidence that such increased cost sharing would not result in an increase in the aggregate costs to the Prescription Drug Insurance Account). See MMA § 201, proposed SSA § 1859G(d)(8) (p. 86).

(308) Provision of data necessary for evaluation of alternative coinsurance proposals. In connection with alternative coinsurance proposals, gather and provide to HHS data and evidence analyzing the differences in projected drug utilization patterns by beneficiaries whose cost sharing would be reduced under the proposal versus those making the cost sharing payments that would otherwise apply. See MMA § 201, proposed SSA § 1859G(d)(8) (p. 86).

(309) Applications for bonus incentive payments relative to efficiencies. Apply for incentive payments based on demonstrated administrative efficiencies, and in accordance with incentive provisions in the HCFA-benefit manager contract. See MMA § 201, proposed SSA § 1859G(g)(1) (p. 88).

(310) Applications for bonus incentive payments relative to savings. Apply for incentive payments based on demonstrated savings achieved, and in accordance with incentive provisions in the HCFA-benefit manager contract. See MMA § 201, proposed SSA § 1859G(g)(2) (p. 88).

(311) Negotiations with HCFA for special risk sharing arrangements. Negotiate specific risk sharing arrangements with HCFA for incorporation into the HCFA-benefit manager contract. See MMA § 201, proposed SSA § 1859G(g)(3) (p. 88).

e. Grievances; dispute resolution.

(312) Implementation of grievance and appeals procedures. Establish and maintain grievance and appeals procedures to address enrollee complaints against the benefit manager or participating pharmacies, in conformity with the regulation to be promulgated by HCFA. See MMA § 201, proposed SSA § 1859G(d)(6)(B) (p. 85).

f. Education.

(313) Implementation of information dissemination mechanism. Have in place mechanisms for disseminating educational and informational materials to enrollees and providers designed to encourage effective and cost-effective use of prescription drugs and to ensure that enrolled individuals understand their rights and obligations under Part D. See MMA § 201, proposed SSA § 1859G(d)(5) (p. 85).

g. Confidentiality.

(314) Implementation of confidentiality requirements. Establish and maintain in effect systems to safeguard the confidentiality of health care information pertaining to enrollees in conformity with 5 U.S.C. §§ 552a and 1106, as well as with such additional standards as may be prescribed by HCFA. See MMA § 201, proposed SSA § 1859G(d)(6)(A) (p. 85).

h. Access.

(315) Adequacy of pharmacy network. Secure the participation of sufficient numbers of pharmacies within the benefit manager's geographic service area to ensure convenient access (including emergency access). See MMA § 201, proposed SSA § 1859G(d)(1)(B)(i) (p. 83).

(316) Pharmacy participation rights. Ensure that any pharmacy in the benefit manager's geographic service area that meets the participation requirements is permitted to participate in the benefit manager's network. See MMA § 201, proposed SSA § 1859G(d)(1)(B)(ii) (p. 83).

(317) Implementation of coordination of benefits requirements. Coordinate with HCFA, other benefit managers, pharmacies, and other relevant entities as necessary to ensure the appropriate coordination of benefits to enrollees. See MMA § 201, proposed SSA § 1859G(d)(3)(B) (p. 84).

(318) Implementation of special outside-the-service-area coordination of benefit requirements. Coordinate with HCFA, other benefit managers, pharmacies, and other relevant entities to ensure that an individual enrollee has access to his or her in-service area coverage when traveling outside the home service area. See MMA § 201, proposed SSA § 1859G(d)(3)(B) (p. 84).

(319) Establishment of rules for pharmacies governing adequacy of access. Develop standards, taking into account the regulations to be promulgated by HCFA, governing access to services to be provided by participating pharmacies. See MMA § 201, proposed SSA § 1859G(e)(2)(B) (p. 87).

i. Cost containment.

(320) Provision of information concerning effectiveness in containing costs. Gather, prepare, and provide to HCFA information on the bidding entity's demonstrable effectiveness in containing costs through pricing incentives and utilization management. See MMA § 201, proposed SSA § 1859G(c)(4)(C) (p. 81).

(321) Regulation governing cost containment. Comply with the cost containment regulation to be promulgated by HCFA. See MMA § 201, proposed SSA § 1859G(c)(4)(C), (e)(2)(B) (pp. 81, 87-88).

j. Quality assurance; error reduction.

(322) Establishment of prescription drug error reduction and quality assurance program. Develop a prescription drug error reduction and quality assurance program. See MMA § 201, proposed SSA § 1859G(c)(3)(C) (p. 80).

(323) Establishment of prescription drug error reduction program. Develop, and include within the proposal, a proposal for working with HCFA to deter medical errors related to prescription drugs. See MMA § 201, proposed SSA § 1859G(c)(3)(F), (d)(4) (pp. 81, 84).

(324) Implementation of quality assurance measures. Have in place effective quality assurance measures. See MMA § 201, proposed SSA § 1859G(d)(4) (p. 84).

(325) Establishment of rules for pharmacies governing quality of services and error reduction. Develop standards, taking into account the regulations to be promulgated by HCFA, governing quality of services and error reduction to be provided by participating pharmacies. See MMA § 201, proposed SSA § 1859G(e)(2)(B) (p. 87).

k. Utilization.

(326) Development of prescription drug utilization management program. Develop a prescription drug cost and utilization management program. See MMA § 201, proposed SSA § 1859G(c)(3)(C) (p. 80).

(327) Implementation of cost and utilization management measures. Implement effective cost and utilization management measures, in conformity with § 1927(g)(2). See MMA § 201, proposed SSA § 1859G(d)(4)(A) (p. 84).

l. Control of fraud, abuse, and waste.

(328) Implementation of program to control fraud, abuse, and waste. Have in place an effective program to control fraud, abuse, and waste. See MMA § 201, proposed SSA § 1859G(d)(4)(B) (p. 85).

m. Oversight and compliance.

(329) Compliance with recordkeeping and reporting requirements. Maintain adequate records, and provide HHS with access to such records (including for audit purposes). Make reports and submissions of financial and utilization data as required by HHS. See MMA § 201, proposed SSA § 1859G(d)(7)(A), (B) (pp. 85-86).

I. Mandates Imposed on Pharmacies.

1. Prescription Drug Benefit Program.

a. Coverage; pricing of prescription drugs.

(330) Compliance with limitations on prices for specific prescription drugs. Ensure that the total charge for each prescription drug dispensed by the pharmacy does not exceed the negotiated price for that drug (*i.e.*, as negotiated by the benefit manager and the manufacturer or other supplier, and as approved by HCFA). See MMA § 201, proposed SSA § 1859G(e)(2)(C) (p. 87).

NOTE: Proposed section 1859G(e)(2) would expressly require that each pharmacy's contract with HCFA state that the pharmacy will "adhere" to the "prices established" by the benefit manager. See MMA § 201, proposed SSA § 1859G(e)(2)(C) (p. 87).

b. Pharmacy contracts with benefit managers; pharmacy responsibilities.

(331) Contracting with benefit manager. Enter into a participation agreement with the benefit manager for the geographic service area in which the pharmacy is located. See MMA § 201, proposed SSA § 1859G(d)(1)(B), (e)(1) (pp. 83, 86).

NOTE: See note at mandate 330, supra.

(332) Compliance with regulation governing pharmacies' quality of services. Comply with the regulation to be promulgated by HCFA governing the quality of services to be provided by pharmacies under Part D. See MMA § 201, proposed SSA § 1859G(e)(2)(B) (p. 87).

(333) Compliance with regulation governing pharmacies' adequacy of access. Comply with the regulation to be promulgated by HCFA governing adequacy of access to services to be provided by pharmacies under Part D. See MMA § 201, proposed SSA § 1859G(e)(2)(B) (p. 87).

(334) Establishment and maintenance of management systems. Establish and maintain management systems (including electronic systems) and procedures for carrying out functions under the participation agreement, in conformity with HCFA and benefit manager requirements. See MMA § 201, proposed SSA § 1859G(e)(2)(D)(i) (p. 87).

(335) Compliance with recordkeeping requirements. Maintain adequate records as the benefit manager may require to enable the benefit manager to meet its responsibilities. See MMA § 201, proposed SSA § 1859G(e)(2)(D)(ii) (p. 87).

(336) Compliance with information access requirements. Provide the benefit manager with access to the pharmacy's records for audit purposes. See MMA § 201, proposed SSA § 1859G(e)(2)(D)(ii) (p. 87).

(337) Compliance with reporting requirements. Make such reports as the benefit manager may require to enable the benefit manager to meet its responsibilities. See MMA § 201, proposed SSA § 1859G(e)(2)(D)(ii) (p. 87).

c. Confidentiality.

(338) Compliance with confidentiality standards. Have in effect systems to ensure compliance with the benefit manager's confidentiality standards. See MMA § 201, proposed SSA § 1859G(e)(2)(F) (p. 88).

d. Access.

(339) Implementation of coordination of benefit requirements in conjunction with HCFA, benefit managers, and other entities. Coordinate with HCFA, benefit managers, and other relevant entities as necessary to ensure the appropriate coordination of benefits to enrollees. See MMA § 201, proposed SSA § 1859G(d)(3)(B) (p. 84).

(340) Implementation of special outside-the-service-area coordination of benefit requirements. Coordinate with HCFA, benefit managers, and other relevant entities to ensure that an individual enrollee has access to his or her in-service area coverage when traveling outside the home service area. See MMA § 201, proposed SSA § 1859G(d)(3)(B) (p. 84).

(341) Adequacy of access. Implement the requirements of the regulation to be promulgated by HCFA governing adequacy of access. See MMA § 201, proposed SSA § 1859G(e)(2)(B) (p. 87).

e. Cost containment.

(342) Implementation of cost management requirements. Implement effective measures for cost management, in accordance with the regulation to be promulgated by HCFA . See MMA § 201, proposed SSA § 1859G(e)(2)(E) (pp. 87-88).

f. Quality assurance; error reduction.

(343) Implementation of quality of services requirements. Implement the requirements of the regulation to be promulgated by HCFA governing quality of services provided by pharmacies. See MMA § 201, proposed SSA § 1859G(e)(2)(B) (p. 87).

(344) Implementation of medical error reduction requirements. Implement effective measures for the reduction of medical errors with respect to prescription drugs dispensed under the participation agreement. See MMA § 201, proposed SSA § 1859G(e)(2)(E) (pp. 87-88).

g. Utilization.

(345) Compliance with recordkeeping requirements pertaining to utilization records. Maintain adequate utilization records, and participate in the benefit manager's utilization review program. See MMA § 201, proposed SSA § 1859G(e)(2)(E) (p. 88).

J. Mandates Imposed on Employer Plans.

1. Prescription Drug Benefit Program.

a. Employer plans.

(346) Annual attestation and assurances with respect to coverage in connection with Employer Incentive Program. Provide annual attestations and assurances required by HCFA to establish that the coverage offered by the sponsor is a qualified retiree prescription drug plan, and will remain such a plan for the duration of the sponsor's participation in the Employer Incentive Program. See MMA § 201, proposed SSA § 1859H(b)(1)(A) (pp. 89-90).

(347) Annual attestation and assurances with respect to required notices in connection with Employer Incentive Program. Provide annual attestations and assurances required by HCFA to guarantee that the sponsor will give notice to HCFA and covered retirees: (i) at least 120 days before terminating the plan; and (ii) immediately upon determining that the actuarial value under the plan falls below the actuarial value of the insurance benefit under Part D. See MMA § 201, proposed SSA § 1859H(b)(1)(B) (p. 90).

(348) Reporting of identities of covered retirees. Report to HCFA annually the names and social security numbers of all retirees (and their spouses and dependents) covered under the retirement plan and the dates during which each individual was covered. See MMA § 201, proposed SSA § 1859H(b)(2) (p. 90).

(349) Compliance with reporting requests in connection with oversight and audits. Maintain, and provide to HHS upon request, such records as HHS may require for the purpose of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage, the accuracy of payments made, and such other matters as may be appropriate. See MMA § 201, proposed SSA § 1859H(b)(3) (p. 90).

(350) Additional reporting requirements in connection with Employer Incentive Program. Provide HHS with additional information, and comply with additional requirements, as HHS deems necessary to administer the Employer Incentive Program. See MMA § 201, proposed SSA § 1859H(b)(4) (p. 90).

K. Mandates Imposed on Medicare+Choice Plans.

1. New Competitive Benefit Package; Establishment of Premium Amounts.

(351) Preparation and submission of bids. Prepare, and submit to HCFA, an annual bid setting forth: notice of intent to offer the plan in specified service areas, information on the service area and plan type, monthly plan bid (*i.e.*, proposed premium amounts), actuarial value of the reduction in cost sharing for Medicare benefits in the bid, description and actuarial value of cost sharing, adjusted community rate of supplemental benefits coverage, and assumptions used with respect to the number of enrolled individuals. See MMA § 101(a)(3), proposed SSA § 1853(c)(1), (2) (pp. 7-8).

(352) Actuarial determinations for bids. Make actuarial determinations necessary to establish a monthly plan bid, including the actuarial value of the reduction in cost sharing for Medicare benefits in the bid. See MMA § 101(a)(3), proposed SSA § 1853(c)(1), (2) (pp. 7-8).

(353) Recordkeeping requirements. Collect, maintain, and report to HCFA data necessary to factor the additional health status and demographic adjustment factors (to be established by HCFA) for use in adjusting bids. See MMA § 101(a)(2), proposed SSA § 1853(b)(4)(D) (pp. 6-7).

(354) Administrative review of challenges to premium and/or cost sharing determinations. Challenge HCFA premium and/or cost sharing determinations through petitions and administrative hearings. See MMA § 101(a), (b) , proposed SSA §§ 1853(d), 1854(c) (pp. 10-12).

(355) Judicial review of premium and/or cost sharing determinations. Challenge HCFA administrative determinations regarding the validity and appropriateness of premium and/or cost sharing. See MMA § 101(a), (b) , proposed SSA §§ 1853(d), 1854(c) (pp. 10-12).

2. Prescription Drug Benefit Program.

a. Enrollment.

(356) Enrollment of Medicare+Choice enrollees in Part D. Assist HCFA in enrolling current Medicare+Choice plan enrollees into the Part D program. See MMA § 201, proposed SSA § 1859C(b) (pp. 73-74).

b. Coverage; pricing of prescription drugs.

(357) Compliance with Part D scope of coverage requirements. Ensure that the plan for Part D benefits guarantees the coverage of any specifically named covered prescription drug for an enrollee when prescribed by a physician, regardless of whether such drug would otherwise be covered under an applicable formulary or discount arrangement. See MMA §201(c)(2)(C), proposed SSA § 1852(d)(1)(F) (p. 97).

c. Reimbursements; funding of program.

(358) Compliance with Part D deductible and coinsurance limitations. Ensure that the Medicare+Choice plan or entity does not include as part of a plan for Part D benefits a deductible or coinsurance percentage that exceeds 50%. See MMA § 201(c)(2)(D), proposed SSA § 1854(e) (p. 97).

d. Access.

(359) Compliance with continuing access requirements. Comply with regulations to be promulgated by HCFA under which enrollees who exhaust the plan's prescription drug benefits will continue to have access to prescription drugs at negotiated prices equivalent to the total combined costs of such drugs to the plan and the enrollee prior to such exhaustion of benefits. See MMA § 201(c)(2)(E), proposed SSA § 1857(d)(6) (p. 97).

L. Mandates Imposed on Medigap Plans.

1. Medigap Updating and Expansion.

(360) Provision of "Plan K" as additional Medigap option. Offer the Plan K option to all Medigap beneficiaries along with Plan A and any other of the existing ten standard Medigap plans. See MMA § 233(a)(1)(B), proposed SSA § 1882(p)(9)(A) (p. 114).

2. Medigap Access.

(361) Expansion of Medigap enrollment opportunities. Comply with the regulation to be promulgated by HCFA governing expansion of Medigap open enrollment opportunities. See MMA § 235(a)(1), proposed SSA § 1882(s) (pp. 117-18).

(362) Expanded Medigap enrollment opportunity for beneficiaries whose other coverage is terminated. Provide revised or expanded opportunity for enrollment in Medigap plans to certain individuals whose other health coverage is terminated. See MMA § 235(b)(1), proposed SSA § 1882(s) (pp. 119-20).

(363) Implementation of Medigap trial period for beneficiaries whose other coverage is terminated. Provide a full 12-month "trial period" in managed care for individuals who are involuntarily terminated from a managed care plan during the trial period if they enroll in another managed care plan. See MMA § 235(b)(2), proposed SSA § 1882(s) (pp. 120-21).

(364) One-time special enrollment period for terminated Medicare+Choice beneficiaries. Provide a one-time Medigap special enrollment period for individuals who lose access to Medicare+Choice plans. See MMA § 235(c), proposed SSA § 1882(s) (pp. 121-22).

(365) Access to all 11 Medigap plan options. Ensure that all 11 Medigap plan options are made available to certain individuals entitled to guaranteed issuance of a Medigap policy after losing other health coverage. See MMA § 235(d), proposed SSA § 1882(s) (p. 123).

M. Mandates Imposed on Providers.

1. Coordination of Care Program.

(366) Proposed reimbursement rate schedule. Develop a proposed reimbursement rate schedule for care coordination services to serve as the basis for negotiations with HCFA. See MMA § 111, proposed SSA § 1866A(e)(2)(B) (p. 22).

(367) Contracting with HCFA. Enter into "care coordination agreements" with HCFA to govern all aspects of the provider's participation in the care coordination services program. See MMA § 111, proposed SSA § 1866A(e)(2) (p. 22).

(368) Enrollment of participants in care coordination program. Enroll individuals desiring to participate in the care coordination program or programs offered by the provider, based on assignment by HCFA. See MMA § 111, proposed SSA § 1866A(c)(1) (pp. 19-20).

(369) Processing of reenrollments and terminations. Process reenrollments and terminations, based on HCFA's determinations for specific individuals. See MMA § 111, proposed SSA § 1866A(c)(2)(B) (p. 20).

(370) Reporting and other compliance-related activities. Respond to inquiries from HCFA regarding performance under the agreement to provide care coordination services. Cooperate with other compliance-related requests of HCFA. See MMA § 111, proposed SSA § 1866A(e)(2)(A) (p. 22).

(371) Defense of administrative enforcement proceedings. Defend against charges of noncompliance with care coordination services agreements in administrative proceedings conducted by HCFA. See MMA § 111, proposed SSA § 1866A(e)(2)(A) (p. 22).

2. Disease Management.

(372) Processing of assigned enrollees. Process enrollment of individuals assigned by HCFA to the entity's disease management program. See MMA § 112, proposed SSA § 1866B(d)(1) (pp. 25-26).

(373) Processing of individual renewals and terminations. Process individual renewals and terminations based on instructions from HCFA. See MMA § 112, proposed SSA § 1866B(d)(1) (pp. 25-26).

(374) Implementation of variations in disease management service packages. Implement variations in disease management service packages offered to specific individuals, based on types of diagnoses, conditions, patient profiles, disease management organization expertise, and other factors HCFA finds appropriate. See MMA § 112, proposed SSA § 1866B(f)(2) (p. 27).

(375) Contracting with HCFA for participation in the disease management program. Enter into agreements with HCFA setting forth the disease management organization's rights and obligations in connection with the provision of disease management items and services. See MMA § 112, proposed SSA § 1866B(g)(2) (pp. 28-29).

(376) Compliance with regulation governing quality of care in connection with the disease management program. Comply with the regulation to be promulgated by HCFA establishing standards for, and procedures for assessing, the quality of care provided by disease management organizations, including performance, licensure, and patient satisfaction standards. See MMA § 112, proposed SSA § 1866B(h)(1) (p. 29).

(377) Compliance with cost management standards for the disease management program. Comply with the regulation to be promulgated by HCFA establishing standards for managing or reducing aggregate costs of health care items or services under the disease management program, including procedures for establishing baselines and for measuring changes in costs. See MMA § 112, proposed SSA § 1866B(h)(2) (pp. 29-30).

(378) Negotiation of reimbursement rates for the disease management program. Conduct negotiations with HCFA concerning payment terms and rates for services provided under the disease management program. See MMA § 112, proposed SSA § 1866B(i)(1) (p. 30).

(379) Responding to compliance monitoring activities and administrative enforcement proceedings in connection with the disease management program. Cooperate with HCFA's compliance monitoring staff undertaking monitoring of the disease management program, including responding to information collections. Participate in administrative proceedings alleging noncompliance with entity obligations under the disease management program. Challenge the imposition of withholding penalties by HCFA. See MMA § 112, proposed SSA § 1866B(h)(1) (p. 29).

(380) Reimbursement rate schedule for disease management program. Develop a proposed reimbursement rate schedule for services to be provided under the disease management program, as a basis for negotiations with HCFA. See MMA § 112, proposed SSA § 1866B(i)(1) (p. 30).

3. Competitive Acquisition Program.

(381) Bidding for competitive acquisition contracts. Bid for contracts to furnish items and services to the Medicare program for specific competitive acquisition areas. See MMA § 113(a), proposed SSA § 1866C(c)(1) (p. 32).

(382) Entering into competitive acquisition contracts. Enter into competitive acquisition agreements with HCFA. See MMA § 113(a), proposed SSA § 1866C(c)(3) (p. 33).

(383) Applications for renewal of competitive acquisition agreements. Apply for periodic renewal of competitive acquisition contracts with HCFA. See MMA § 113(a), proposed SSA § 1866C(c)(3) (p. 33).

(384) Performance standards for competitive acquisition program. Comply with the performance standards to be promulgated by HCFA for the competitive acquisition program. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(385) Reporting and other compliance-related activities. Respond to inquiries from HCFA regarding performance under the competitive acquisition contract. Cooperate with other compliance-related requests of HCFA. See MMA § 118(a), proposed SSA § 1866M(b)(6) (pp. 47-48).

(386) Defense of administrative enforcement proceedings. Defend against charges of noncompliance with the competitive acquisition contract or regulations in administrative proceedings conducted by HCFA. See MMA § 118(a), proposed SSA § 1866M(b)(7) (p. 48).

4. Provider-Physician Collaboration Program.

(387) Contracting with HCFA. Enter into agreements with beneficiaries for the provision of items and services pursuant to provider-physician collaboration arrangements. See MMA § 114, proposed SSA § 1866D(e) (p. 35).

(388) Contracting with beneficiaries in connection with provider-physician collaboration program. Enter into agreements with individual beneficiaries for the provision of bundled Medicare items and services pursuant to provider-physician collaborations. See MMA § 114, proposed SSA § 1866D(f) (p. 35).

(389) Compliance with regulation governing disclosures to beneficiaries in connection with provider-physician collaborations. Comply with the regulation to be promulgated by HCFA setting forth the disclosures that must be made to beneficiaries before they enter into agreements to receive items and services pursuant to provider-physician collaboration agreements, as well as the terms of agreements between beneficiaries and collaboration entities. See MMA § 114, proposed SSA § 1866D(f) (p. 35).

(390) Compliance with performance standards for provider-physician collaboration program. Comply with the performance standards for the provider-physician collaboration program to be established by HCFA. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(391) Reporting and other compliance-related activities. Respond to inquiries from HCFA regarding performance under the provider-physician collaboration contract. Cooperate with other compliance-related requests of HCFA. See MMA § 114, proposed SSA § 1866D (pp. 34-35).

(392) Defense of administrative enforcement proceedings. Defend against charges of noncompliance with the provider-physician collaboration contract or regulations in administrative proceedings conducted by HCFA. See MMA § 114, proposed SSA § 1866D (pp. 34-35).

5. Preferred Participants Program.

(393) Contracting with HCFA in connection with the preferred participants program. Enter into contracts with HCFA setting forth the rights and obligations arising from certification as a "preferred participant." See MMA § 115(a), proposed SSA § 1866E(a)(1) (pp. 35-36).

(394) Preferred provider reimbursement rates. Develop a proposed preferred provider reimbursement rate schedule for negotiation with HCFA. See MMA § 115(a), proposed SSA § 1866E(b)(1)(B) (pp. 36-37).

(395) Compliance with regulation for determining cost sharing reductions in connection with the preferred participants program. Comply with the regulation to be promulgated by HCFA for determining the extent of beneficiary cost sharing reductions or elimination under the preferred participant program. See MMA § 115(a), proposed SSA § 1866E(c) (p. 37).

(396) Compliance with performance standards for preferred participants program. Comply with the performance standards for the preferred participants program to be established by HCFA. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(397) Reporting and other compliance-related activities. Respond to inquiries from HCFA regarding performance under the preferred participants contract. Cooperate with other compliance-related requests of HCFA. See MMA § 115(a), proposed SSA § 1866E (pp. 35-37).

(398) Defense of administrative enforcement proceedings. Defend against charges of noncompliance with the preferred-participants contract or regulations in administrative proceedings conducted by HCFA. See MMA § 115(a), proposed SSA § 1866E (pp. 35-37).

6. Centers of Excellence.

(399) Competitive bidding for participation in centers of excellence program. Prepare a bid to obtain a contract with HCFA for the furnishing of bundled groups of items and services related to certain surgical and non-surgical procedures furnished during an episode of care. See MMA § 116(a), proposed SSA § 1866F(a)(1) (p. 38).

(400) Quality assurance program for centers of excellence program. Establish a quality assurance program for implementation in connection with the centers of excellence program. See MMA § 116(a), proposed SSA § 1866F(b)(2) (p. 38).

(401) Reimbursements in connection with the centers of excellence program. Prepare reimbursement requests based on the inclusive, bundled rating schedule approved by HCFA. See MMA § 116(a), proposed SSA § 1866F(c)(1) (p. 39).

(402) Contract renewal. Apply for renewal of contracts with HCFA to provide bundled items and services pursuant to the centers of excellence program. See MMA § 116(a), proposed SSA § 1866F(d) (p. 39).

(403) Compliance with performance and quality standards for centers of excellence program. Comply with the performance and quality standards for the centers of excellence program to be established by HCFA. See MMA § 118(a), proposed SSA § 1866M(b)(5) (pp. 46-47).

(404) Reporting and other compliance-related activities. Respond to inquiries from HCFA regarding performance under the centers of excellence contract. Cooperate with other compliance-related requests of HCFA. See MMA § 116(a), proposed SSA § 1866F (pp. 37-40).

(405) Defense of administrative enforcement proceedings. Defend against charges of noncompliance with the centers of excellence contract or regulations in administrative proceedings conducted by HCFA. See MMA § 116(a), proposed SSA § 1866F (pp. 37-40).

7. Bonus Payments Demonstration Project.

(406) Applications for participation in the bonus demonstration project. Prepare applications for participation in the bonus demonstration project, and submit the same to HCFA. See MMA § 117, proposed SSA § 1866G(b)(1) (pp. 41-42).

(407) Contracting with HCFA for participation in the bonus demonstration project. Enter into contracts with HCFA for participation in the bonus demonstration project. See MMA § 117, proposed SSA § 1866G(b)(2) (p. 42).

(408) Selection of demonstration project participants. Assist HCFA in identifying patients in the health care group for participation in the bonus demonstration project. See MMA § 117, proposed SSA § 1866G(c)(2) (pp. 42-43).

(409) Performance standards for bonus payments demonstration project. Comply with the performance standards for the bonus payments for health care groups demonstration program to be established by HCFA. See MMA § 118, proposed SSA § 1866M(b)(5) (pp. 46-47).

(410) Reporting and other compliance-related activities. Respond to inquiries from HCFA regarding performance under the bonus payments demonstration project. Cooperate with other compliance-related requests of HCFA. See MMA § 117, proposed SSA § 1866G (pp. 40-44).

(411) Defense of administrative enforcement proceedings. Defend against charges of noncompliance with requirements of the bonus payments demonstration project in administrative proceedings conducted by HCFA. See MMA § 117, proposed SSA § 1866G (pp. 40-44).

8. Reports to Congress.

(412) Provider reporting requirements in support of HCFA report to Congress. Provide information required by HCFA to enable HCFA to prepare the report to Congress required by mandate 251. See MMA § 119 (p. 57).

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