

Monday 4:14 PM
B

AMENDMENT #9

OFFERED BY MR. BURGESS OF TEXAS

Amend Title VII Medicaid and CHIP Part 4 "Coverage". After Section 1733 insert the following:

Section 1734: Ryan Dant Health Care Opportunity

SEC. 1. STATE OPTION TO DISREGARD CERTAIN INCOME IN PROVIDING CONTINUED MEDICAID COVERAGE FOR CERTAIN INDIVIDUALS WITH EXTREMELY HIGH PRESCRIPTION COSTS.

Section 1902(e) of the Social Security Act (42 U.S.C. 1396b(e)), as amended by section 203(a) of the Children's Health Insurance Program Reauthorization Act of 2009 (Public Law 111-3), is amended by adding at the end the following new paragraph:

`(14)(A) At the option of the State, in the case of an individual with extremely high prescription drug costs described in subparagraph (B) who has been determined (without the application of this paragraph) to be eligible for medical assistance under this title, the State may, in redetermining the individual's eligibility for medical assistance under this title, disregard any family income of the individual to the extent such income is less than an amount that is specified by the State and does not exceed the amount specified in subparagraph (C), or, if greater, income equal to the cost of the orphan drugs described in subparagraph (B)(iii).

`(B) An individual with extremely high prescription drug costs described in this subparagraph for a 12-month period is an individual--

`(i) who is covered under health insurance or a health benefits plan that has a maximum lifetime limit of not less than \$1,000,000 which includes all prescription drug coverage;

`(ii) who has exhausted all available prescription drug coverage under the plan as of the beginning of such period;

`(iii) who incurs (or is reasonably expected to incur) on an annual basis during the period costs for orphan drugs in excess of the amount specified in subparagraph (C) for the period; and

`(iv) whose annual family income (determined without regard to this paragraph) as of the beginning of the period does not exceed 75 percent of the amount incurred for such drugs (as described in clause (iii)).

`(C) The amount specified in this subparagraph for a 12-month period beginning in--

`(i) 2009 or 2010, is \$200,000; or

`(ii) a subsequent year, is the amount specified in clause (i) (or this subparagraph) for the previous year increased by the annual rate of increase in the medical care component of the consumer price index (U.S. city average) for the 12-month period ending in August of the previous year.

Any amount computed under clause (ii) that is not a multiple of \$1,000 shall be rounded to the nearest multiple of \$1,000.

`(D) In applying this paragraph, amounts incurred for prescription drugs for cosmetic purposes shall not be taken into account.

`(E) With respect to an individual described in subparagraph (A), notwithstanding section 1916, the State plan--

`(i) shall provide for the application of cost-sharing that is at least nominal as determined under section 1916; and

`(ii) may provide, consistent with section 1916A, for such additional cost-sharing as does not exceed a maximum level of cost-sharing that is specified by the Secretary and is adjusted by the Secretary on an annual basis.

`(F) A State electing the option under this paragraph shall provide for a determination on an individual's application for continued medical assistance under this title within 30 days of the date the application is filed with the State.

`(G) In this paragraph:

`(i) The term 'orphan drugs' means prescription drugs designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) as a drug for a rare disease or condition.

`(ii) The term 'health benefits plan' includes coverage under a plan offered under a State high risk pool.'

Fr: 7/31
2:32 pm
A

AMENDMENT #36A

**OFFERED BY MR. BURGESS OF TEXAS AND MR. BARROW OF
GEORGIA**

In section 132 (relating to grievance and appeals mechanisms) strike “(a) IN GENERAL” and all that follows and insert: “A QHBP offering entity shall provide for timely grievance and appeals mechanisms as the Commissioner shall establish.”.

Add at the end of subtitle D of title I of division A (relating to consumer protections) the following new sections:

SEC. 138. UTILIZATION REVIEW ACTIVITIES.

(a) COMPLIANCE WITH REQUIREMENTS.—

(1) IN GENERAL.—A qualified health benefits plan, and a QHBP offering entity that offers such plan, shall conduct utilization review activities in connection with the provision of benefits under such plan only in accordance with a utilization review program that meets the requirements of this section.

(2) USE OF OUTSIDE AGENTS.—Nothing in this section shall be construed as preventing a qualified health benefits plan or QHBP offering entity from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the plan entity, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.

(3) UTILIZATION REVIEW DEFINED.—For purposes of this section, the terms “utilization review” and “utilization review activities” mean procedures used to monitor or evaluate the use or coverage, clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.

(b) WRITTEN POLICIES AND CRITERIA.—

(1) WRITTEN POLICIES.—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.

(2) USE OF WRITTEN CRITERIA.—

(A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed with input from a range of appropriate actively practicing health care professionals, as determined by the plan, pursuant to the program. Such criteria shall include written clinical review criteria that are based on valid clinical evidence where available and that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate.

(B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.—If a health care service has been specifically pre-authorized or approved for an enrollee under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the enrollee during the same course of treatment.

(C) REVIEW OF SAMPLE OF CLAIMS DENIALS.—Such a program shall provide for an evaluation of the clinical appropriateness of at least a sample of denials of claims for benefits.

(c) CONDUCT OF PROGRAM ACTIVITIES.—

(1) ADMINISTRATION BY HEALTH CARE PROFESSIONALS.—A utilization review program shall be

administered by qualified health care professionals who shall oversee review decisions.

(2) USE OF QUALIFIED, INDEPENDENT PERSONNEL.—

(A) IN GENERAL.—A utilization review program shall provide for the conduct of utilization review activities only through personnel who are qualified and have received appropriate training in the conduct of such activities under the program.

(B) PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS.—Such a program shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that encourages denials of claims for benefits.

(C) PROHIBITION OF CONFLICTS.—Such a program shall not permit a health care professional who is providing health care services to an individual to perform utilization review activities in connection with the health care services being provided to the individual.

(3) ACCESSIBILITY OF REVIEW.—Such a program shall provide that appropriate personnel performing utilization review activities under the program, including the utilization review administrator, are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.

(4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.

(d) DEADLINE FOR DETERMINATIONS.—

(1) PRIOR AUTHORIZATION SERVICES.—

(A) IN GENERAL.—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the case, and in no event later than the deadline specified in subparagraph (B).

(B) DEADLINE.—

(i) IN GENERAL.—Subject to clauses (ii), (iii), and (iv) the deadline specified in this subparagraph is 14 days after the date of receipt of the request for prior authorization, but in no event later than 3 business days after the date of receipt of information that is reasonably necessary to make such determination.

(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDITIONAL INFORMATION REQUIRED.—If a utilization review program—

(I) receives a request for a prior authorization;

(II) determines that additional information is necessary to complete the review and make the determination on the request; and

(III) notifies the requester, not later than 5 business days after the date of receiving the request, of the need for such specified additional information;

the deadline specified in this subparagraph is 14 days after the date the program receives the specified additional information, but in no case later than 28 days after the date of receipt of the request for the prior authorization. This clause shall not apply if the deadline is specified in clause (iii).

(iii) EXPEDITED CASES.—In the case of a situation described in section 139(c)(1)(A), the deadline specified in this subparagraph is 72 hours after the time of the request for prior authorization.

(iv) Exception for emergency services.—No prior approval shall be required in the case of emergency services provided by a hospital.

(2) ONGOING CARE.—

(A) CONCURRENT REVIEW.—

(i) IN GENERAL.—Subject to subparagraph (B), in the case of a concurrent review of ongoing care (including hospitalization), which results in a termination or reduction of such care, the plan must provide by telephone and in printed form notice of the concurrent review determination to the individual or the individual's designee and the individual's health care provider as soon as possible in accordance with the medical exigencies of the case, and in no event later than 1 business day after the date of receipt of information that is reasonably necessary to make such determination, with sufficient time prior to the termination or reduction to allow for an appeal under section 139(c)(1)(A) to be

completed before the termination or reduction takes effect.

(ii) CONTENTS OF NOTICE.—Such notice shall include, with respect to ongoing health care items and services, the number of ongoing services approved, the new total of approved services, the date of onset of services, and the next review date, if any, as well as a statement of the individual's rights to further appeal.

(B) EXCEPTION.—Subparagraph (A) shall not be interpreted as requiring plans or issuers to provide coverage of care that would exceed the coverage limitations for such care.

(3) PREVIOUSLY PROVIDED SERVICES.—In the case of a utilization review activity involving retrospective review of health care services previously provided for an individual, the utilization review program shall make a determination concerning such services, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, within 30 days of the date of receipt of information that is reasonably necessary to make such determination, but in no case later than 60 days after the date of receipt of the claim for benefits.

(4) FAILURE TO MEET DEADLINE.—In a case in which a qualified health benefits plan or QHBP offering entity fails to make a determination on a claim for benefit under paragraph (1), (2)(A), or (3) by the applicable deadline established under the respective paragraph, the failure shall be treated under this subtitle as a denial of the claim as of the date of the deadline.

(e) NOTICE OF DENIALS OF CLAIMS FOR BENEFITS.—

(1) IN GENERAL.—Notice of a denial of claims for benefits under a utilization review program shall be provided in printed form and written in a manner calculated to be

understood by the participant, beneficiary, or enrollee and shall include—

(A) the reasons for the denial (including the clinical rationale);

(B) instructions on how to initiate an appeal under section 138; and

(C) notice of the availability, upon request of the individual (or the individual's designee) of the clinical review criteria relied upon to make such denial.

(2) SPECIFICATION OF ANY ADDITIONAL INFORMATION.—Such a notice shall also specify what (if any) additional necessary information must be provided to, or obtained by, the person making the denial in order to make a decision on such an appeal.

(f) CLAIM FOR BENEFITS AND DENIAL OF CLAIM FOR BENEFITS DEFINED.—For purposes of this subtitle:

(1) CLAIM FOR BENEFITS.—The term “claim for benefits” means any request for coverage (including authorization of coverage), for eligibility, or for payment in whole or in part, for an item or service under a qualified health benefits plan.

(2) DENIAL OF CLAIM FOR BENEFITS.—The term “denial” means, with respect to a claim for benefits, means a denial, or a failure to act on a timely basis upon, in whole or in part, the claim for benefits and includes a failure to provide benefits (including items and services) required to be provided under this title.

SEC. 139. INTERNAL APPEALS PROCEDURES.

(a) RIGHT OF REVIEW.—

(1) IN GENERAL.—Each qualified health benefits plan, and each QHBP offering entity offering such plan—

(A) shall provide adequate notice in writing to any participant or beneficiary under such plan, or enrollee under such coverage, whose claim for benefits under the plan has been denied (within the meaning of section 137(f)(2)), setting forth the specific reasons for such denial of claim for benefits and rights to any further review or appeal, written in a manner calculated to be understood by the participant, beneficiary, or enrollee; and

(B) shall afford such a participant, beneficiary, or enrollee (and any provider or other person acting on behalf of such an individual with the individual's consent or without such consent if the individual is medically unable to provide such consent) who is dissatisfied with such a denial of claim for benefits a reasonable opportunity (of not less than 180 days) to request and obtain a full and fair review by a named fiduciary (with respect to such plan) or named appropriate individual (with respect to such coverage) of the decision denying the claim.

(2) TREATMENT OF ORAL REQUESTS.—The request for review under paragraph (1)(B) may be made orally, but, in the case of an oral request, shall be followed by a request in writing.

(b) INTERNAL REVIEW PROCESS.—

(1) CONDUCT OF REVIEW.—

(A) IN GENERAL.—A review of a denial of claim under this section shall be made by an individual who—

(i) in a case involving medical judgment, shall be a physician or, in the case of limited scope coverage (as defined in subparagraph (B)), shall be an appropriate specialist;

(ii) has been selected by the plan or entity; and

(iii) did not make the initial denial in the internally appealable decision.

(B) LIMITED SCOPE COVERAGE DEFINED.—For purposes of subparagraph (A), the term “limited scope coverage” means a qualified health benefits plan the only benefits under which are for benefits described in section 2791(c)(2)(A) of the Public Health Service Act (42 U.S.C. 300gg-91(c)(2)).

(2) TIME LIMITS FOR INTERNAL REVIEWS.—

(A) IN GENERAL.—Having received such a request for review of a denial of claim, the QHBP offering entity offering a qualified health benefits plan, in accordance with the medical exigencies of the case but not later than the deadline specified in subparagraph (B), complete the review on the denial and transmit to the participant, beneficiary, enrollee, or other person involved a decision that affirms, reverses, or modifies the denial. If the decision does not reverse the denial, the plan or issuer shall transmit, in printed form, a notice that sets forth the grounds for such decision and that includes a description of rights to any further appeal. Such decision shall be treated as the final decision of the plan. Failure to issue such a decision by such deadline shall be treated as a final decision affirming the denial of claim.

(B) DEADLINE.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), the deadline specified in this subparagraph is 14 days after the date of receipt of the request for internal review.

(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDITIONAL INFORMATION REQUIRED.—If a qualified health benefits plan of QHBP offering entity—

(I) receives a request for internal review,

(II) determines that additional information is necessary to complete the review and make the determination on the request, and

(III) notifies the requester, not later than 5 business days after the date of receiving the request, of the need for such specified additional information,

the deadline specified in this subparagraph is 14 days after the date the plan or entity receives the specified additional information, but in no case later than 28 days after the date of receipt of the request for the internal review. This clause shall not apply if the

deadline is specified in clause (iii).

(iii) EXPEDITED CASES.—In the case of a situation described in subsection (c)(1)(A), the deadline specified in this subparagraph is 72 hours after the time of the request for review.

(c) EXPEDITED REVIEW PROCESS.—

(1) IN GENERAL.—A qualified health benefits plan, and a QHBP offering entity, shall establish procedures in writing for the expedited consideration of requests for review under subsection (b) in situations—

(A) in which, as determined by the plan or issuer or as certified in writing by a treating health care professional, the application of the normal timeframe for making a determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee or such an individual's ability to regain maximum function; or

(B) described in section 137(d)(2) (relating to requests for continuation of ongoing care which would otherwise be reduced or terminated).

(2) PROCESS.—Under such procedures—

(A) the request for expedited review may be submitted orally or in writing by an individual or provider who is otherwise entitled to request the review;

(B) all necessary information, including the plan's or entity's decision, shall be transmitted between the plan or issuer and the requester by telephone, facsimile, or other similarly expeditious available method; and

(C) the plan or issuer shall expedite the review in the case of any of the situations described in subparagraph (A) or (B) of paragraph (1).

(3) DEADLINE FOR DECISION.—The decision on the expedited review must be made and communicated to the parties as soon as possible in accordance with the medical exigencies of the case, and in no event later than 72 hours after the time of receipt of the request for expedited review, except that in a case described in paragraph (1)(B), the decision must be made before the end of the approved period of care.

(d) WAIVER OF PROCESS.—A plan or entity may waive its rights for an internal review under subsection (b). In such case the participant, beneficiary, or enrollee involved (and any designee or provider involved) shall be relieved of any obligation to complete the review involved and may, at the option of such participant, beneficiary, enrollee, designee, or provider, proceed directly to seek further appeal through any applicable external appeals process.

SEC. 140. EXTERNAL APPEALS PROCEDURES.

(a) RIGHT TO EXTERNAL APPEAL.—

(1) IN GENERAL.—A qualified health benefits plan, and a QHBP offering entity, shall provide for an external appeals process that meets the requirements of this section in the case of an externally appealable decision described in paragraph (2), for which a timely appeal is made either by the plan or entity or by the participant, beneficiary, or enrollee (and any provider or other person acting on behalf of such an individual with the individual's consent or without such consent if such an individual is medically unable to provide such consent). The appropriate Secretary shall establish standards to carry out such requirements.

(2) EXTERNALLY APPEALABLE DECISION DEFINED.—

(A) IN GENERAL.—For purposes of this section, the term 'externally appealable decision' means a denial of claim for benefits (as defined in section 137(f)(2))—

(i) that is based in whole or in part on a decision that the item or service is not medically necessary or appropriate or is investigational or experimental; or

(ii) in which the decision as to whether a benefit is covered involves a medical judgment.

(B) INCLUSION.—Such term also includes a failure to meet an applicable deadline for internal review under section 138.

(C) EXCLUSIONS.—Such term does not include—

(i) specific exclusions or express limitations on the amount, duration, or scope of coverage that do not involve medical judgment; or

(ii) a decision regarding whether an individual is a participant, beneficiary, or enrollee under the plan.

(3) EXHAUSTION OF INTERNAL REVIEW PROCESS.— Except as provided under section 138(d), a plan or entity may condition the use of an external appeal process in the case of an externally appealable decision upon a final decision in an internal review under section 138, but only if the decision is made in a timely basis consistent with the deadlines provided under this subtitle.

(4) FILING FEE REQUIREMENT.—

(A) IN GENERAL.—Subject to subparagraph (B), a plan or entity may condition the use of an external appeal process upon payment to the plan or entity of a filing fee that does not exceed \$25.

(B) EXCEPTION FOR INDIGENCY.—The plan or issuer may not require payment of the filing fee in the case of an individual participant, beneficiary, or enrollee who certifies (in a form and manner specified in

guidelines established by the Secretary of Health and Human Services) that the individual is indigent (as defined in such guidelines).

(C) REFUNDING FEE IN CASE OF SUCCESSFUL APPEALS.—The plan or entity shall refund payment of the filing fee under this paragraph if the recommendation of the external appeal entity is to reverse or modify the denial of a claim for benefits which is the subject of the appeal.

(b) GENERAL ELEMENTS OF EXTERNAL APPEALS PROCESS.—

(1) CONTRACT WITH QUALIFIED EXTERNAL APPEAL ENTITY.—

(A) CONTRACT REQUIREMENT.—Except as provided in subparagraph (D), the external appeal process under this section of a plan or entity shall be conducted under a contract between the plan or issuer and one or more qualified external appeal entities (as defined in subsection (c)).

(B) LIMITATION ON PLAN OR ISSUER SELECTION.—The applicable authority shall implement procedures—

(i) to assure that the selection process among qualified external appeal entities will not create any incentives for external appeal entities to make a decision in a biased manner, and

(ii) for auditing a sample of decisions by such entities to assure that no such decisions are made in a biased manner.

(C) OTHER TERMS AND CONDITIONS.—The terms and conditions of a contract under this paragraph shall be consistent with the standards the appropriate Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external

appeal activities. Such contract shall provide that all costs of the process (except those incurred by the participant, beneficiary, enrollee, or treating professional in support of the appeal) shall be paid by the plan or entity, and not by the participant, beneficiary, or enrollee. The previous sentence shall not be construed as applying to the imposition of a filing fee under subsection (a)(4).

(D) STATE AUTHORITY WITH RESPECT TO QUALIFIED EXTERNAL APPEAL ENTITY FOR HEALTH INSURANCE ISSUERS.—With respect to QHBP offering entities offering qualified health benefits plans in a State, the State may provide for external review activities to be conducted by a qualified external appeal entity that is designated by the State or that is selected by the State in a manner determined by the State to assure an unbiased determination.

(2) ELEMENTS OF PROCESS.—An external appeal process shall be conducted consistent with standards established by the appropriate Secretary that include at least the following:

(A) FAIR AND DE NOVO DETERMINATION.—The process shall provide for a fair, de novo determination. However, nothing in this paragraph shall be construed as providing for coverage of items and services for which benefits are specifically excluded under the plan.

(B) STANDARD OF REVIEW.—An external appeal entity shall determine whether the plan's or issuer's decision is in accordance with the medical needs of the patient involved (as determined by the entity) taking into account, as of the time of the entity's determination, the patient's medical condition and any relevant and reliable evidence the entity obtains under subparagraph (D). If the entity determines the decision is in accordance with such needs, the entity shall affirm the decision and to the extent that the entity determines the decision is not in

accordance with such needs, the entity shall reverse or modify the decision.

(C) CONSIDERATION OF PLAN OR COVERAGE DEFINITIONS.—In making such determination, the external appeal entity shall consider (but not be bound by) any language in the plan or coverage document relating to the definitions of the terms medical necessity, medically necessary or appropriate, or experimental, investigational, or related terms.

(D) EVIDENCE.—

(i) IN GENERAL.—An external appeal entity shall include, among the evidence taken into consideration—

(I) the decision made by the plan or QHBP offering entity upon internal review under section 138 and any guidelines or standards used by the plan or QHBP offering entity in reaching such decision;

(II) any personal health and medical information supplied with respect to the individual whose denial of claim for benefits has been appealed; and

(III) the opinion of the individual's treating physician or health care professional.

(ii) ADDITIONAL EVIDENCE.—Such external appeal entity may also take into consideration but not be limited to the following evidence (to the extent available):

(I) The results of studies that meet professionally recognized standards of validity and replicability or that have been published in peer-reviewed journals.

(II) The results of professional consensus conferences conducted or financed in whole or in part by one or more government agencies.

(III) Practice and treatment guidelines prepared or financed in whole or in part by government agencies.

(IV) Government-issued coverage and treatment policies.

(V) Community standard of care and generally accepted principles of professional medical practice.

(VI) To the extent that the entity determines it to be free of any conflict of interest, the opinions of individuals who are qualified as experts in one or more fields of health care which are directly related to the matters under appeal.

(VII) To the extent that the entity determines it to be free of any conflict of interest, the results of peer reviews conducted by the plan involved.

(E) DETERMINATION CONCERNING EXTERNALLY APPEALABLE DECISIONS.—A qualified external appeal entity shall determine—

(i) whether a denial of claim for benefits is an externally appealable decision (within the meaning of subsection (a)(2));

(ii) whether an externally appealable decision involves an expedited appeal; and

(iii) for purposes of initiating an external review, whether the internal review process has been completed.

(F) OPPORTUNITY TO SUBMIT EVIDENCE.—Each party to an externally appealable decision may submit evidence related to the issues in dispute.

(G) PROVISION OF INFORMATION.—The plan or issuer involved shall provide timely access to the external appeal entity to information and to provisions of the plan relating to the matter of the externally appealable decision, as determined by the entity.

(H) TIMELY DECISIONS.—A determination by the external appeal entity on the decision shall—

(i) be made orally or in writing and, if it is made orally, shall be supplied to the parties in writing as soon as possible;

(ii) be made in accordance with the medical exigencies of the case involved, but in no event later than 21 days after the date (or, in the case of an expedited appeal, 72 hours after the time) of requesting an external appeal of the decision;

(iii) state, in layperson's language, the basis for the determination, including, if relevant, any basis in the terms or conditions of the plan; and

(iv) inform the participant, beneficiary, or enrollee of the individual's rights (including any limitation on such rights) to seek further review by the courts (or other process) of the external appeal determination.

(I) COMPLAINT WITH DETERMINATION.—If the external appeal entity reverses or modifies the denial of a claim for benefits, the plan shall—

(i) upon the receipt of the determination, authorize benefits in accordance with such determination;

(ii) take such actions as may be necessary to provide benefits (including items or services) in a timely manner consistent with such determination; and

(iii) submit information to the entity documenting compliance with the entity's determination and this subparagraph.

(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTITIES.—

(1) IN GENERAL.—For purposes of this section, the term 'qualified external appeal entity' means, in relation to a plan or issuer, an entity that is certified under paragraph (2) as meeting the following requirements:

(A) The entity meets the independence requirements of paragraph (3).

(B) The entity conducts external appeal activities through a panel of not fewer than 3 clinical peers.

(C) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan on a timely basis consistent with subsection (b)(2)(G).

(D) The entity meets such other requirements as the appropriate Secretary may impose.

(2) INITIAL CERTIFICATION OF EXTERNAL APPEAL ENTITIES.—

(A) IN GENERAL.—In order to be treated as a qualified external appeal entity with respect to—

(i) a qualified health benefits plan that is a group health plan, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting the requirements of paragraph (1)—

(I) by the Secretary of Labor;

(II) under a process recognized or approved by the Secretary of Labor; or

(III) to the extent provided in subparagraph (C)(i), by a qualified private standard-setting organization (certified under such subparagraph); or

(ii) a QHBP offering entity that is a health insurance issuer operating in a State, the qualified external appeal entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting such requirements—

(I) by the applicable State authority (or under a process recognized or approved by such authority); or

(II) if the State has not established a certification and recertification process for such entities, by the Secretary of Health and Human Services, under a process recognized or approved by such Secretary, or to the extent provided in subparagraph (C)(ii), by a qualified private standard-setting organization (certified under such subparagraph).

(B) RECERTIFICATION PROCESS.—The appropriate Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a review of—

- (i) the number of cases reviewed;
- (ii) a summary of the disposition of those cases;
- (iii) the length of time in making determinations on those cases;
- (iv) updated information of what was required to be submitted as a condition of certification for the entity's performance of external appeal activities; and
- (v) such information as may be necessary to assure the independence of the entity from the plans or issuers for which external appeal activities are being conducted.

(C) CERTIFICATION OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—

(i) FOR EXTERNAL REVIEWS OF GROUP HEALTH PLANS.—For purposes of subparagraph (A)(i)(III), the Secretary of Labor may provide for a process for certification (and periodic recertification) of qualified private standard-setting organizations which provide for certification of external review entities. Such an organization shall only be certified if the organization does not certify an external review entity unless it meets standards required for certification of such an entity by such Secretary under subparagraph (A)(i)(I).

(ii) FOR EXTERNAL REVIEWS OF HEALTH INSURANCE ISSUERS.—For purposes of subparagraph (A)(ii)(II), the Secretary of Health and Human Services may provide for a process for certification (and periodic recertification) of qualified private standard-setting organizations which provide for certification of external review

entities. Such an organization shall only be certified if the organization does not certify an external review entity unless it meets standards required for certification of such an entity by such Secretary under subparagraph (A)(ii)(II).

(3) INDEPENDENCE REQUIREMENTS.—

(A) IN GENERAL.—A clinical peer or other entity meets the independence requirements of this paragraph if—

(i) the peer or entity does not have a familial, financial, or professional relationship with any related party;

(ii) any compensation received by such peer or entity in connection with the external review is reasonable and not contingent on any decision rendered by the peer or entity;

(iii) except as provided in paragraph (4), the plan and the issuer have no recourse against the peer or entity in connection with the external review; and

(iv) the peer or entity does not otherwise have a conflict of interest with a related party as determined under any regulations which the Secretary may prescribe.

(B) RELATED PARTY.—For purposes of this paragraph, the term 'related party' means—

(i) with respect to—

(I) a qualified health benefits plan that is a group health plan, the plan or QHBP offering entity of such plan; or

(II) a qualified health benefits plan that is individual health insurance coverage, the health insurance issuer offering such coverage, or any plan sponsor, fiduciary, officer, director, or management employee of such plan or issuer;

(ii) the health care professional that provided the health care involved in the coverage decision;

(iii) the institution at which the health care involved in the coverage decision is provided;

(iv) the manufacturer of any drug or other item that was included in the health care involved in the coverage decision; or

(v) any other party determined under any regulations which the Secretary may prescribe to have a substantial interest in the coverage decision.

(4) LIMITATION ON LIABILITY OF REVIEWERS.—No qualified external appeal entity having a contract with a qualified health benefits plan under this part and no person who is employed by any such entity or who furnishes professional services to such entity, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this section, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) if due care was exercised in the performance of such duty, function, or activity and there was no actual malice or gross misconduct in the performance of such duty, function, or activity.

(d) EXTERNAL APPEAL DETERMINATION BINDING ON PLAN.—The determination by an external appeal entity under this section is binding on the plan involved in the determination.

(e) PENALTIES AGAINST AUTHORIZED OFFICIALS FOR REFUSING TO AUTHORIZE THE DETERMINATION OF AN EXTERNAL REVIEW ENTITY.—

(1) MONETARY PENALTIES.—In any case in which the determination of an external review entity is not followed by a qualified health benefits plan, any person who, acting in the capacity of authorizing the benefit, causes such refusal may, in the discretion in a court of competent jurisdiction, be liable to an aggrieved participant, beneficiary, or enrollee for a civil penalty in an amount of up to \$1,000 a day from the date on which the determination was transmitted to the plan by the external review entity until the date the refusal to provide the benefit is corrected.

(2) CEASE AND DESIST ORDER AND ORDER OF ATTORNEY'S FEES.—In any action described in paragraph (1) brought by a participant, beneficiary, or enrollee with respect to a qualified health benefits plan, in which a plaintiff alleges that a person referred to in such paragraph has taken an action resulting in a refusal of a benefit determined by an external appeal entity in violation of such terms of the plan, coverage, or this subtitle, or has failed to take an action for which such person is responsible under the plan or this title and which is necessary under the plan or coverage for authorizing a benefit, the court shall cause to be served on the defendant an order requiring the defendant—

(A) to cease and desist from the alleged action or failure to act; and

(B) to pay to the plaintiff a reasonable attorney's fee and other reasonable costs relating to the prosecution of the action on the charges on which the plaintiff prevails.

(3) ADDITIONAL CIVIL PENALTIES.—

(A) IN GENERAL.—In addition to any penalty imposed under paragraph (1) or (2), the appropriate Secretary may assess a civil penalty against a person acting in the capacity of authorizing a benefit

determined by an external review entity for one or more qualified health benefits plans, for—

(i) any pattern or practice of repeated refusal to authorize a benefit determined by an external appeal entity in violation of the terms of such a plan, or this title; or

(ii) any pattern or practice of repeated violations of the requirements of this section with respect to such plan or plans.

(B) STANDARD OF PROOF AND AMOUNT OF PENALTY.—Such penalty shall be payable only upon proof by clear and convincing evidence of such pattern or practice and shall be in an amount not to exceed the lesser of—

(i) 25 percent of the aggregate value of benefits shown by the appropriate Secretary to have not been provided, or unlawfully delayed, in violation of this section under such pattern or practice, or

(ii) \$500,000.

(4) REMOVAL AND DISQUALIFICATION.—Any person acting in the capacity of authorizing benefits who has engaged in any such pattern or practice described in paragraph (3)(A) with respect to a plan or coverage, upon the petition of the appropriate Secretary, may be removed by the court from such position, and from any other involvement, with respect to such a plan or coverage, and may be precluded from returning to any such position or involvement for a period determined by the court.

(f) PROTECTION OF LEGAL RIGHTS.—Nothing in this subtitle shall be construed as altering or eliminating any cause of action or legal rights or remedies of participants, beneficiaries, enrollees, and others under State or Federal law (including sections 502 and 503 of the Employee Retirement

Income Security Act of 1974), including the right to file judicial actions to enforce actions.

(g) APPLICATION TO ALL ACCEPTABLE COVERAGE.—The provisions of this section shall apply with respect to all acceptable coverage in the same manner as such provisions apply with respect to qualified health benefits plans under this section.

Thurs
7/30 11:40pm
C

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 3200
OFFERED BY MR. BUTTERFIELD OF NORTH
CAROLINA**

(AINS-EC_001)

In title V of division C, add at the end the following
new subtitle:

**1 Subtitle F—Grants to Implement
2 Medication Management Serv-
3 ices in Treatment of Chronic
4 Diseases**

**5 SEC. 2551. GRANTS TO IMPLEMENT MEDICATION MANAGE-
6 MENT SERVICES IN TREATMENT OF CHRONIC
7 DISEASES.**

8 (a) IN GENERAL.—The Secretary of Health and
9 Human Services, acting through the Director of the Agen-
10 cy for Health Care Research and Quality, shall establish
11 a program to provide grants to eligible entities to imple-
12 ment medication management services (referred to in this
13 section as “MTM services”) provided by licensed phar-
14 macists, as a part of a collaborative, multidisciplinary,
15 inter-professional approach to the treatment of chronic
16 diseases for targeted individuals, to improve the quality

1 of care and reduce overall cost in the treatment of such
2 diseases. The Secretary shall commence the grant pro-
3 gram not later than May 1, 2010.

4 (b) **ELIGIBLE ENTITIES.**—To be eligible to receive a
5 grant under subsection (a), an entity shall—

6 (1) provide a setting appropriate for MTM serv-
7 ices, as recommended by the experts described in
8 subsection (e);

9 (2) submit to the Secretary a plan for achieving
10 long-term financial sustainability;

11 (3) where applicable, submit a plan for coordi-
12 nating MTM services with other local providers and
13 where applicable, through or in collaboration with
14 the Medicare Medical Home Pilot program as estab-
15 lished by section 1866E of the Social Security Act,
16 as added by section 1302 of this Act;

17 (4) submit a plan for meeting the requirements
18 under subsection (e); and

19 (5) submit to the Secretary such other informa-
20 tion as the Secretary may require.

21 (c) **MTM SERVICES TO TARGETED INDIVIDUALS.**—

22 The MTM services provided with the assistance of a grant
23 awarded under subsection (a) shall, as allowed by State
24 law (including applicable collaborative pharmacy practice
25 agreements), include—

1 (1) performing or obtaining necessary assess-
2 ments of the health and functional status of each
3 patient receiving such MTM services;

4 (2) formulating an medication treatment plan
5 according to therapeutic goals agreed upon by the
6 prescriber and the patient or caregiver or authorized
7 representative of the patient;

8 (3) selecting, initiating, modifying, recom-
9 mending changes to, or administering medication
10 therapy;

11 (4) monitoring, which may include access to, or-
12 dering, or performing laboratory assessments, and
13 evaluating the response of the patient to therapy, in-
14 cluding safety and effectiveness;

15 (5) performing an initial comprehensive medica-
16 tion review to identify, resolve, and prevent medica-
17 tion-related problems, including adverse drug events,
18 quarterly targeted medication reviews for ongoing
19 monitoring, and additional follow-up interventions
20 on a schedule developed collaboratively with the pre-
21 scriber;

22 (6) documenting the care delivered and commu-
23 nicating essential information about such care (in-
24 cluding a summary of the medication review) and
25 the recommendations of the pharmacist to other ap-

1 appropriate health care providers of the patient in a
2 timely fashion;

3 (7) providing education and training designed
4 to enhance the understanding and appropriate use of
5 the medications by the patient, caregiver, and other
6 authorized representative;

7 (8) providing information, support services, and
8 resources and strategies designed to enhance patient
9 adherence with therapeutic regimens;

10 (9) coordinating and integrating MTM services
11 within the broader health care management services
12 provided to the patient; and

13 (10) such other patient care services as are al-
14 lowed under the scopes of practice for pharmacist
15 for purposes of other Federal programs.

16 (d) TARGETED INDIVIDUALS.—MTM services pro-
17 vided by licensed pharmacists under a grant awarded
18 under subsection (a) shall be offered to targeted individ-
19 uals who—

20 (1) take 4 or more prescribed medications (in-
21 cluding over-the-counter and dietary supplements);

22 (2) take any high risk medications;

23 (3) have 2 or more chronic diseases, as identi-
24 fied by the Secretary; or

1 (4) have undergone a transition of care, or
2 other factors, as determined by the Secretary, that
3 are likely to create a high risk of medication-related
4 problems.

5 (e) CONSULTATION WITH EXPERTS.—In designing
6 and implementing MTM services provided under grants
7 awarded under subsection (a), the Secretary shall consult
8 with Federal, State, private, public-private, and academic
9 entities, pharmacy and pharmacist organizations, health
10 care organizations, consumer advocates, chronic disease
11 groups, and other stakeholders involved with the research,
12 dissemination, and implementation of pharmacist-deliv-
13 ered MTM services, as the Secretary determines appro-
14 priate. The Secretary, in collaboration with this group,
15 shall determine whether it is possible to incorporate rapid
16 cycle process improvement concepts in use in other Fed-
17 eral programs that have implemented MTM services.

18 (f) REPORTING TO THE SECRETARY.—An entity that
19 receives a grant under subsection (a) shall submit to the
20 Secretary a report that describes and evaluates, as re-
21 quested by the Secretary, the activities carried out under
22 subsection (c), including quality measures, as determined
23 by the Secretary.

1 (g) EVALUATION AND REPORT.—The Secretary shall
2 submit to the relevant committees of Congress a report
3 which shall—

4 (1) assess the clinical effectiveness of phar-
5 macist-provided services under the MTM services
6 program, as compared to usual care, including an
7 evaluation of whether enrollees maintained better
8 health with fewer hospitalizations and emergency
9 room visits than similar patients not enrolled in the
10 program;

11 (2) assess changes in overall health care re-
12 source of targeted individuals;

13 (3) assess patient and prescriber satisfaction
14 with MTM services;

15 (4) assess the impact of patient-cost sharing re-
16 quirements on medication adherence and rec-
17 ommendations for modifications;

18 (5) identify and evaluate other factors that may
19 impact clinical and economic outcomes, including de-
20 mographic characteristics, clinical characteristics,
21 and health services use of the patient, as well as
22 characteristics of the regimen, pharmacy benefit,
23 and MTM services provided; and

24 (6) evaluate the extent to which participating
25 pharmacists who maintain a dispensing role have a

1 conflict of interest in the provision of MTM services,
2 and if such conflict is found, provide recommenda-
3 tions on how such a conflict might be appropriately
4 addressed.

5 (h) GRANT TO FUND DEVELOPMENT OF PERFORM-
6 ANCE MEASURES.—Secretary may award grants or con-
7 tracts to eligible entities for the purpose of funding the
8 development of performance measures that assess the use
9 and effectiveness of medication therapy management serv-
10 ices.



Fri 7/31
1:58pm
A

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 3200
OFFERED BY MR. MELANCON OF LOUISIANA
(AINS-EC_001)**

At the end of section 102(e), add the following:

1 (3) STAND-ALONE DENTAL AND VISION COV-
2 ERAGE PERMITTED.—Nothing in this division shall
3 be construed—

4 (A) to prevent the offering of a stand-alone
5 plans that offer coverage of excepted benefits
6 described in section 2791(c)(2)(A) of the Public
7 Health Service Act (relating to limited scope
8 dental or vision benefits)for individuals and
9 families from a State licensed dental and vision
10 carrier; or

11 (B) as applying requirements for a quali-
12 fied health benefits plan to such stand-alone
13 plans that is offered and priced separately from
14 a qualified health benefits plan.

Add at the end of section 122 the following: “”.

15 ~~(d) [REDACTED]~~
16 ~~[REDACTED]~~

1 ~~(1) **NO APPLICATION TO ADULT COVERAGE.**—~~
2 ~~Nothing in this subtitle shall be construed as requir-~~
3 ~~ing an individual who is 21 years of age or older to~~
4 ~~be provided coverage described in paragraph (1).~~
5 ~~(2) **TREATMENT OF COMBINED COVERAGE.**—~~
6 ~~The combination of stand-alone coverage described~~
7 ~~in paragraph (1) and a qualified health benefits plan~~
8 ~~without coverage of such oral and vision services~~
9 ~~shall be treated as satisfying the essential benefits~~
10 ~~package under this division.~~
11 ~~Nothing in this subtitle shall be construed as requir-~~
12 ~~ing an individual who is 21 years of age or older to~~
13 ~~be provided coverage described in paragraph (1).~~
14 ~~(3) **NO APPLICATION TO ADULT COVERAGE.**—~~
15 ~~Nothing in this subtitle shall be construed as requir-~~
16 ~~ing an individual who is 21 years of age or older to~~
17 ~~be provided coverage described in paragraph (1).~~
18 ~~(4) **TREATMENT OF COMBINED COVERAGE.**—~~
19 ~~The combination of stand-alone coverage described~~
20 ~~in paragraph (1) and a qualified health benefits plan~~
21 ~~without coverage of such oral and vision services~~
 shall be treated as satisfying the essential benefits
 package under this division.

