SENATE BILL No. 1193

March 6, 2002, Introduced by Senators SCHWARZ, SHUGARS, JOHNSON, BYRUM, EMERSON and NORTH and referred to the Committee on Health Policy.

A bill to amend 1939 PA 280, entitled

"The social welfare act,"

(MCL 400.1 to 400.119b) by adding sections 111k, 111*l*, 111m, 111n, 111o, 111p, 111q, and 111r.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

SEC. 111K. AS USED IN SECTIONS 111*l* TO 111R:

(A) "BOARD" MEANS THE DRUG UTILIZATION REVIEW BOARD ESTABLISHED UNDER SECTION 111M.

(B) "COMMITTEE" MEANS THE PHARMACY AND THERAPEUTICS COMMITTEE ESTABLISHED UNDER SECTION 111P.

(C) "COMPENDIA" MEANS THE "AMERICAN HOSPITAL FORMULARY SERVICES DRUG INFORMATION", "U.S. PHARMACOPEIA--DRUG INFORMATION", PEER-REVIEWED MEDICAL LITERATURE, AND CLINICAL INFORMATION SUBMITTED TO THE DEPARTMENT OF COMMUNITY HEALTH BY THE PHARMACEUTICAL RESEARCH COMPANY THAT DEVELOPED THE PRODUCT AND IS

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REGISTERED WITH THE UNITED STATES FOOD AND DRUG ADMINISTRATION AS THE PRODUCT DISTRIBUTOR.

(D) "DUR CRITERIA" MEANS STANDARDS APPROVED BY THE BOARD TO DETERMINE WHETHER USE OF A DRUG IS LIKELY TO BE MEDICALLY APPROPRIATE, BE MEDICALLY NECESSARY, AND NOT RESULT IN AN ADVERSE MEDICAL OUTCOME.

(E) "DRUG UTILIZATION REVIEW" OR "DUR" MEANS BOTH RETROSPECTIVE AND PROSPECTIVE DRUG UTILIZATION REVIEW. DUR PROGRAMS ARE DESIGNED TO ENSURE THAT DRUG UTILIZATION IS MEDICALLY APPROPRIATE, MEDICALLY NECESSARY, AND NOT LIKELY TO HAVE ADVERSE MEDICAL RESULTS.

(F) "PRIOR AUTHORIZATION" MEANS A PROCESS REQUIRING THE PRESCRIBER OR THE DISPENSER TO VERIFY WITH THE STATE DEPARTMENT OF COMMUNITY HEALTH OR ITS CONTRACTOR THAT PROPOSED MEDICAL USE OF A PARTICULAR MEDICINE FOR A PATIENT MEETS PREDETERMINED CRITERIA FOR COVERAGE BY THE PROGRAM.

(G) "PROSPECTIVE DUR" MEANS THAT PART OF THE DRUG UTILIZATION REVIEW PROGRAM THAT OCCURS BEFORE A DRUG IS DISPENSED AND THAT USES THE DUR CRITERIA TO SCREEN FOR POTENTIAL DRUG THERAPY PROBLEMS RELATED TO THERAPEUTIC DUPLICATION, DRUG-DISEASE CONTRAINDICATIONS, DRUG-DRUG INTERACTIONS, INCORRECT DRUG DOSAGE OR DURATION OF DRUG TREATMENT, DRUG-ALLERGY INTERACTIONS, AND CLINICAL ABUSE OR MISUSE.

(H) "RETROSPECTIVE DUR" MEANS THAT PART OF THE DRUG UTILIZATION REVIEW PROGRAM THAT IS A HISTORICAL REVIEW OF DRUG UTILIZATION DATA USING DUR CRITERIA TO EXAMINE PHARMACY CLAIMS DATA AND OTHER INFORMATION TO IDENTIFY OVERUTILIZATION, UNDERUTILIZATION,

APPROPRIATE USE OF GENERIC PRODUCTS, THERAPEUTIC DUPLICATION, DRUG-DISEASE CONTRAINDICATIONS, DRUG-DRUG INTERACTIONS, INCORRECT DRUG DOSAGE OR DURATION OF DRUG TREATMENT, AND CLINICAL ABUSE OR MISUSE.

SEC. 111*l*. THE LEGISLATURE RECOGNIZES THAT OUTPATIENT PRESCRIPTION DRUGS ARE AN ESSENTIAL COMPONENT OF PATIENT CARE AND, AS A HEALTH BENEFITS PAYER UNDER THE STATE'S MEDICAL ASSISTANCE PROGRAM, THE LEGISLATURE DIRECTS THE DEPARTMENT OF COMMUNITY HEALTH TO ADD A PRIOR AUTHORIZATION COMPONENT TO ITS DRUG UTILIZATION REVIEW PROGRAM TO ENSURE THAT BENEFICIARIES HAVE ACCESS TO MEDICALLY NECESSARY MEDICINES IN A CLINICALLY APPROPRIATE AND COST-EFFECTIVE MANNER.

SEC. 111M. (1) THE DRUG UTILIZATION REVIEW BOARD IS ESTABLISHED WITHIN THE DEPARTMENT OF COMMUNITY HEALTH FOR THE PURPOSE OF IMPLEMENTING A RETROSPECTIVE AND PROSPECTIVE DRUG UTILIZATION REVIEW PROGRAM.

(2) THE BOARD SHALL CONSIST OF 11 MEMBERS APPOINTED BY THE DIRECTOR OF THE DEPARTMENT OF COMMUNITY HEALTH TO INCLUDE ALL OF THE FOLLOWING:

(A) FOUR PHYSICIANS LICENSED UNDER ARTICLE 15 OF THE PUBLIC HEALTH CODE, 1978 PA 368, MCL 333.16101 TO 333.18838, ACTIVELY ENGAGED IN THE PRACTICE OF MEDICINE, AND CHOSEN FROM A LIST OF NOMINEES PROVIDED BY THE MICHIGAN MEDICAL SOCIETY.

(B) FIVE PHARMACISTS LICENSED UNDER ARTICLE 15 OF THE PUBLIC HEALTH CODE, 1978 PA 368, MCL 333.16101 TO 333.18838, ACTIVELY ENGAGED IN THE PRACTICE OF PHARMACY, AND CHOSEN FROM A LIST OF NOMINEES PROVIDED BY THE MICHIGAN PHARMACY ASSOCIATION.

(C) ONE RESIDENT OF THIS STATE REPRESENTING MEDICAL ASSISTANCE PROGRAM BENEFICIARIES.

(D) ONE RESIDENT OF THIS STATE REPRESENTING THE PHARMACEUTICAL INDUSTRY CHOSEN FROM A LIST OF NOMINEES PROVIDED BY THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA.

(3) BOARD MEMBERS SHALL SERVE STAGGERED 3-YEAR TERMS. ONE PHYSICIAN, 1 PHARMACIST, AND THE BENEFICIARY REPRESENTATIVE SHALL EACH BE INITIALLY APPOINTED FOR 2 YEARS, AND 1 PHYSICIAN, 2 PHARMACISTS, AND THE INDUSTRY REPRESENTATIVE SHALL EACH BE INITIALLY APPOINTED FOR 1 YEAR. MEMBERS MAY BE REAPPOINTED FOR A PERIOD NOT TO EXCEED 3 THREE-YEAR TERMS. VACANCIES ON THE BOARD SHALL BE FILLED FOR THE BALANCE OF THE UNEXPIRED TERM FROM NOMINEE LISTS FOR THE APPROPRIATE BOARD CATEGORY AS UNDER SUBSECTION (2).

(4) BOARD MEMBERS SHALL SELECT A CHAIRPERSON AND A VICE CHAIRPERSON ON AN ANNUAL BASIS FROM THE BOARD MEMBERSHIP.

(5) THE BOARD SHALL MEET AT LEAST 6 TIMES EACH YEAR AND MAY MEET AT OTHER TIMES AT THE DISCRETION OF THE CHAIRPERSON. NOTICE OF A MEETING OF THE BOARD SHALL BE PUBLISHED IN THE MICHIGAN BULLETIN 30 DAYS BEFORE THE MEETING. BOARD MEETINGS SHALL COMPLY WITH THE OPEN MEETINGS ACT, 1976 PA 267, MCL 15.261 TO 15.275. BOARD MEETINGS ARE SUBJECT TO THE ADMINISTRATIVE PROCEDURES ACT OF 1969, 1969 PA 306, 24.201 TO 24.328.

SEC. 111N. THE BOARD SHALL DO ALL OF THE FOLLOWING:

(A) ADVISE AND MAKE RECOMMENDATIONS REGARDING RULES PROMULGATED BY THE DEPARTMENT OF COMMUNITY HEALTH IMPLEMENTING STATE AND FEDERAL LAW RELATED TO DRUG UTILIZATION REVIEW.

(B) OVERSEE IMPLEMENTATION OF A RETROSPECTIVE AND PROSPECTIVE DUR PROGRAM FOR THE MEDICAL ASSISTANCE PROGRAM, INCLUDING RESPONSIBILITY FOR RECOMMENDING CRITERIA FOR SELECTION OF CONTRACTORS AND REVIEWING CONTRACTS BETWEEN THE MEDICAL ASSISTANCE PROGRAM AND ANY OTHER ENTITY THAT WILL PROCESS AND REVIEW DRUG CLAIMS AND PROFILES FOR THE DUR PROGRAM IN ACCORDANCE WITH SECTIONS 111*l* TO 111R.

(C) DEVELOP AND APPLY THE DUR CRITERIA FOR THE RETROSPECTIVE AND PROSPECTIVE DUR PROGRAMS AND ENSURE THAT THE DUR CRITERIA ARE CONSISTENT WITH THE INDICATIONS SUPPORTED OR REJECTED BY THE COMPENDIA AND UNITED STATES FOOD AND DRUG ADMINISTRATION APPROVED LABELING FOR THE DRUG. THE BOARD SHALL CONSIDER OUTSIDE INFORMATION PROVIDED BY INTERESTED PARTIES, INCLUDING PRESCRIBERS WHO TREAT SIGNIFICANT NUMBERS OF PATIENTS UNDER THE MEDICAL ASSISTANCE PROGRAM.

(D) ESTABLISH A PROCESS TO REASSESS THE DUR CRITERIA ON A PERIODIC BASIS AND MODIFY THE PROSPECTIVE AND RETROSPECTIVE DUR PROGRAMS, AS NECESSARY.

(E) PROVIDE A PERIOD FOR PUBLIC COMMENT DURING EACH BOARD MEETING AND FURNISH NOTICE OF PROPOSED CHANGES TO THE DUR CRITERIA AND MODIFICATION OF THE PROSPECTIVE AND RETROSPECTIVE DUR PROGRAMS 30 DAYS BEFORE CONSIDERING OR RECOMMENDING A PROPOSED CHANGE TO THE DUR PROGRAMS.

SEC. 111o. (1) THE BOARD, IN COOPERATION WITH THE DEPARTMENT OF COMMUNITY HEALTH, SHALL CREATE AND IMPLEMENT A PROSPECTIVE AND RETROSPECTIVE DUR PROGRAM FOR OUTPATIENT PRESCRIPTION DRUGS UNDER THE MEDICAL ASSISTANCE PROGRAM, USING DUR CRITERIA TO

ENSURE THAT DRUG UTILIZATION IS MEDICALLY APPROPRIATE, MEDICALLY NECESSARY, AND NOT LIKELY TO RESULT IN ADVERSE MEDICAL OUTCOMES.

(2) THE DEPARTMENT OF COMMUNITY HEALTH MAY CONTRACT WITH AN ENTITY TO PROCESS AND REVIEW DRUG CLAIMS AND PROFILES FOR THE DUR PROGRAM. THE DEPARTMENT OF COMMUNITY HEALTH SHALL USE A COMPETITIVE BIDDING PROCESS AS REQUIRED UNDER SECTION 261 OF THE MANAGEMENT AND BUDGET ACT, 1984 PA 431, MCL 18.1261.

(3) THE PROSPECTIVE DUR PROGRAM SHALL BE BASED ON DUR CRITERIA ESTABLISHED BY THE BOARD AND SHALL PROVIDE THAT, BEFORE A PRESCRIPTION IS FILLED OR DELIVERED, A REVIEW SHALL BE CONDUCTED BY A PHARMACIST AT THE POINT OF SALE TO SCREEN FOR A POTENTIAL DRUG THERAPY PROBLEM. IN CONDUCTING THE PROSPECTIVE DUR REVIEW, A PHARMACIST SHALL NOT ALTER THE PRESCRIBED OUTPATIENT DRUG THERAPY WITHOUT A NEW PRESCRIPTION ORDER BY THE PRESCRIBING PHYSICIAN AND APPROVAL BY THE PATIENT. THE PROSPECTIVE DUR REVIEW SHALL SCREEN FOR ALL OF THE FOLLOWING:

(A) THERAPEUTIC DUPLICATION.

(B) DRUG-DISEASE CONTRAINDICATIONS.

(C) DRUG-DRUG INTERACTIONS.

(D) INCORRECT DRUG DOSAGE OR DURATION OF DRUG TREATMENT.

(E) DRUG-ALLERGY INTERACTIONS.

(F) CLINICAL ABUSE OR MISUSE.

(4) THE RETROSPECTIVE DUR PROGRAM SHALL BE BASED ON DUR CRITERIA ESTABLISHED BY THE BOARD USING THE DEPARTMENT OF COMMUNITY HEALTH'S MECHANIZED DRUG CLAIMS PROCESSING AND INFORMATION RETRIEVAL SYSTEM TO ANALYZE MEDICAL ASSISTANCE CLAIMS TO DO ALL OF THE FOLLOWING:

(A) IDENTIFY PATTERNS OF FRAUD, ABUSE, GROSS OVERUSE OR UNDERUSE, OR INAPPROPRIATE OR MEDICALLY UNNECESSARY CARE.

(B) ASSESS DATA ON DRUG USE BY APPLYING AND REVIEWING CRITERIA DEVELOPED FROM THE COMPENDIA OR UNITED STATES FOOD AND DRUG ADMINISTRATION APPROVED LABELING FOR THE PURPOSE OF EVALUATING ALL OF THE FOLLOWING:

(*i*) THERAPEUTIC APPROPRIATENESS.

(*ii*) OVERUTILIZATION OR UNDERUTILIZATION.

(*iii*) APPROPRIATE USE OF GENERIC PRODUCTS.

(*iv*) THERAPEUTIC DUPLICATION.

(*v*) DRUG-DISEASE CONTRAINDICATIONS.

(*vi*) DRUG-DRUG INTERACTIONS.

(*vii*) INCORRECT DRUG DOSAGE OR DURATION OF DRUG TREATMENT.

(*viii*) CLINICAL ABUSE OR MISUSE.

(C) PROPOSE REMEDIAL STRATEGIES TO IMPROVE THE QUALITY OF CARE AND PROMOTE EFFECTIVE USE OF MEDICAL ASSISTANCE PROGRAM FUNDS OR BENEFICIARY EXPENDITURES.

SEC. 111P. (1) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, THE DEPARTMENT OF COMMUNITY HEALTH MAY IMPLEMENT A PRIOR AUTHORIZATION PROGRAM FOR OUTPATIENT PRESCRIPTION DRUGS UNDER THE MEDICAL ASSISTANCE PROGRAM ONLY AS PROVIDED IN SECTIONS 111*l* TO 111R.

(2) THE PHARMACY AND THERAPEUTICS COMMITTEE IS ESTABLISHED WITHIN THE DEPARTMENT OF COMMUNITY HEALTH FOR THE PURPOSES OF IMPLEMENTING PRIOR AUTHORIZATION FOR OUTPATIENT PRESCRIPTION DRUGS UNDER THE MEDICAL ASSISTANCE PROGRAM.

(3) THE COMMITTEE SHALL CONSIST OF 11 MEMBERS APPOINTED BY THE DIRECTOR OF THE DEPARTMENT OF COMMUNITY HEALTH TO INCLUDE ALL OF THE FOLLOWING:

(A) FIVE PHYSICIANS LICENSED UNDER ARTICLE 15 OF THE PUBLIC HEALTH CODE, 1978 PA 368, MCL 333.16101 TO 333.18838, ACTIVELY ENGAGED IN THE PRACTICE OF MEDICINE, AND CHOSEN FROM A LIST OF NOMINEES PROVIDED BY THE MICHIGAN MEDICAL SOCIETY.

(B) FOUR PHARMACISTS LICENSED UNDER ARTICLE 15 OF THE PUBLIC HEALTH CODE, 1978 PA 368, MCL 333.16101 TO 333.18838, ACTIVELY ENGAGED IN THE PRACTICE OF PHARMACY, AND CHOSEN FROM A LIST OF NOMINEES PROVIDED BY THE MICHIGAN PHARMACY ASSOCIATION.

(C) ONE RESIDENT OF THIS STATE REPRESENTING MEDICAL ASSISTANCE PROGRAM BENEFICIARIES.

(D) ONE RESIDENT OF THIS STATE REPRESENTING THE PHARMACEUTICAL INDUSTRY CHOSEN FROM A LIST OF NOMINEES PROVIDED BY THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA.

(4) COMMITTEE MEMBERS SHALL SERVE STAGGERED 3-YEAR TERMS. TWO PHYSICIANS, 1 PHARMACIST, AND THE MEDICAL ASSISTANCE BENEFICIARY REPRESENTATIVE SHALL EACH BE INITIALLY APPOINTED FOR 2-YEAR TERMS, AND 1 PHYSICIAN, 1 PHARMACIST, AND THE INDUSTRY REPRESENTATIVE SHALL EACH BE INITIALLY APPOINTED FOR 1-YEAR TERMS. MEMBERS MAY BE REAPPOINTED FOR A PERIOD NOT TO EXCEED 3 THREE-YEAR TERMS. VACANCIES ON THE COMMITTEE SHALL BE FILLED FOR THE BALANCE OF THE UNEXPIRED TERM FROM NOMINEE LISTS FOR THE APPROPRIATE COMMITTEE CATEGORY AS UNDER SUBSECTION (3).

(5) COMMITTEE MEMBERS SHALL SELECT A CHAIRPERSON AND A VICE CHAIRPERSON ON AN ANNUAL BASIS FROM THE COMMITTEE MEMBERSHIP.

(6) THE COMMITTEE SHALL MEET AT LEAST 6 TIMES EACH YEAR AND MAY MEET AT OTHER TIMES AT THE DISCRETION OF THE CHAIRPERSON. NOTICE OF A MEETING OF THE COMMITTEE SHALL BE PUBLISHED IN THE MICHIGAN BULLETIN 30 DAYS BEFORE THE MEETING. COMMITTEE MEETINGS SHALL COMPLY WITH THE PROVISIONS OF THE OPEN MEETINGS ACT, 1976 PA 267, MCL 15.261 TO 15.275. COMMITTEE MEETINGS ARE SUBJECT TO THE PROVISIONS OF THE ADMINISTRATIVE PROCEDURES ACT OF 1969, 1969 PA 306, MCL 24.201 TO 24.328.

SEC. 111Q. THE COMMITTEE SHALL DO ALL OF THE FOLLOWING:

(A) ADVISE AND MAKE RECOMMENDATIONS REGARDING RULES PROMULGATED BY THE DEPARTMENT REGARDING OUTPATIENT PRESCRIPTION DRUG PRIOR AUTHORIZATION.

(B) OVERSEE THE IMPLEMENTATION OF A DRUG PRIOR AUTHORIZATION PROGRAM FOR THE MEDICAL ASSISTANCE PROGRAM.

(C) ESTABLISH THE DRUG PRIOR AUTHORIZATION REVIEW PROCESS IN COMPLIANCE WITH SECTION 111R.

(D) MAKE FORMAL RECOMMENDATIONS TO THE DEPARTMENT REGARDING ANY OUTPATIENT PRESCRIPTION DRUG COVERED BY THE MEDICAL ASSISTANCE PROGRAM REQUIRING PRIOR AUTHORIZATION.

(E) REVIEW ON A SEMIANNUAL BASIS WHETHER DRUGS PLACED ON PRIOR AUTHORIZATION ARE TO REMAIN ON PRIOR AUTHORIZATION.

(F) IF NECESSARY, MODIFY THE PRIOR AUTHORIZATION REVIEW PROCESS TO ACHIEVE THE OBJECTIVES OF THIS ACT.

SEC. 111R. (1) A DRUG PRIOR AUTHORIZATION PROGRAM SHALL MEET ALL OF THE FOLLOWING CONDITIONS:

(A) THE PROGRAM SHALL PROVIDE TELEPHONE, FACSIMILE, OR OTHER ELECTRONICALLY TRANSMITTED APPROVAL OR DENIAL WITHIN 24 HOURS AFTER RECEIPT OF THE PRIOR AUTHORIZATION REQUEST.

(B) IN AN EMERGENCY SITUATION, INCLUDING A SITUATION IN WHICH A RESPONSE TO A PRIOR AUTHORIZATION REQUEST IS UNAVAILABLE, A 72-HOUR SUPPLY OF THE PRESCRIBED DRUG SHALL BE DISPENSED AND PAID FOR BY THE MEDICAL ASSISTANCE PROGRAM OR, AT THE DISCRETION OF THE COMMITTEE, A SUPPLY GREATER THAN 72 HOURS THAT WILL ASSURE A MINIMUM EFFECTIVE DURATION OF THERAPY FOR AN ACUTE INTERVENTION.

(C) AUTHORIZATION SHALL BE GRANTED IF THE DRUG IS PRESCRIBED FOR A MEDICALLY ACCEPTED USE SUPPORTED BY EITHER THE COMPENDIA, APPROVED PRODUCT LABELING, OR PEER-REVIEWED LITERATURE UNLESS THERE IS A THERAPEUTICALLY EQUIVALENT GENERIC DRUG THAT IS AVAIL-ABLE WITHOUT PRIOR AUTHORIZATION.

(D) THE DRUG UTILIZATION REVIEW PROGRAM ADMINISTRATORS SHALL CONSULT WITH PRESCRIBERS TO DEVELOP A STREAMLINED PROCESS FOR THE PRESCRIBER TO FURNISH ANY DOCUMENTATION REQUIRED TO SUPPORT A PRIOR AUTHORIZATION REQUEST, INCLUDING, BUT NOT LIMITED TO, NAME, TITLE, ADDRESS, AND TELEPHONE NUMBER OF THE PRESCRIBER MAKING THE REQUEST, DATE OF THE REQUEST, THE PRODUCT NAME OF THE REQUESTED DRUG, A DESCRIPTION OF THE CIRCUMSTANCES AND BASIS FOR THE REQUEST, AND WHETHER THE REQUEST IS AN EMERGENCY. THE PROCESS SHALL FLOW DIRECTLY FROM THE PATIENT CARE INTERACTION. THE DEPARTMENT OF COMMUNITY HEALTH SHALL NOT REQUIRE A SEPARATE SET OF TASKS OF THE PRESCRIBER.

(2) THE COMMITTEE SHALL NOT RECOMMEND A DRUG FOR PRIOR AUTHORIZATION, AND THE DEPARTMENT OF COMMUNITY HEALTH SHALL NOT PLACE A DRUG ON PRIOR AUTHORIZATION, UNLESS ALL OF THE FOLLOWING CONDITIONS ARE MET:

(A) THE COMMITTEE ANALYZES THE RETROSPECTIVE DUR DATA USING THE DUR CRITERIA TO IDENTIFY A DRUG, USE OF WHICH IS LIKELY NOT TO BE MEDICALLY APPROPRIATE OR MEDICALLY NECESSARY OR IS LIKELY TO RESULT IN AN ADVERSE MEDICAL OUTCOME.

(B) THE COMMITTEE CONSIDERS THE POTENTIAL IMPACT ON PATIENT CARE AND THE POTENTIAL FISCAL IMPACT THAT MAY RESULT FROM A DRUG ON PRIOR AUTHORIZATION.

(C) ANY CONSIDERATION OF THE COST OF THE DRUG BY THE COMMITTEE SHALL REFLECT THE TOTAL COST OF TREATING THE CONDITIONS FOR WHICH THE DRUG IS PRESCRIBED, INCLUDING NONPHARMACEUTICAL COSTS AND COSTS INCURRED BY OTHER SECTORS OF THE STATE HEALTH CARE PROGRAM THAT MAY BE AFFECTED BY THE DRUG'S AVAILABILITY FOR USE IN TREATING MEDICAL ASSISTANCE PROGRAM BENEFICIARIES.

(D) THE COMMITTEE PROVIDES 30 DAYS' PUBLIC NOTICE PRIOR TO EACH MEETING DEVELOPING RECOMMENDATIONS CONCERNING WHETHER A DRUG SHOULD BE PLACED ON PRIOR AUTHORIZATION. ANY INTERESTED PARTY MAY REQUEST AN OPPORTUNITY TO MAKE AN ORAL PRESENTATION TO THE COMMITTEE RELATED TO THE PRIOR AUTHORIZATION OF THE DRUG. THE COMMITTEE SHALL ALSO CONSIDER ANY INFORMATION PROVIDED BY ANY INTERESTED PARTY, INCLUDING, BUT NOT LIMITED TO, PHYSICIANS, PHARMACISTS, BENEFICIARIES, AND MANUFACTURERS OR DISTRIBUTORS OF THE DRUG.

(E) THE COMMITTEE MAKES A FORMAL WRITTEN RECOMMENDATION TO THE DEPARTMENT OF COMMUNITY HEALTH THAT A DRUG BE PLACED ON PRIOR AUTHORIZATION THAT IS SUPPORTED BY AN ANALYSIS OF PROSPECTIVE AND RETROSPECTIVE DUR DATA DEMONSTRATING ALL OF THE FOLLOWING:

(*i*) THE EXPECTED IMPACT OF A DECISION ON THE CLINICAL CARE LIKELY TO BE RECEIVED BY BENEFICIARIES FOR WHOM THE DRUG IS MEDICALLY NECESSARY.

(*ii*) THE EXPECTED IMPACT ON PHYSICIANS WHOSE PATIENTS REQUIRE THE DRUG.

(*iii*) THE EXPECTED FISCAL IMPACT ON THE MEDICAL ASSISTANCE PROGRAM.

(F) THE DEPARTMENT OF COMMUNITY HEALTH ACCEPTS OR REJECTS THE RECOMMENDATION OF THE COMMITTEE AND, IN A WRITTEN DECISION, DETERMINES WHETHER A DRUG SHALL BE PLACED ON PRIOR AUTHORIZATION. THE DEPARTMENT OF COMMUNITY HEALTH MAY CONSIDER ANY ADDITIONAL AND CLARIFYING INFORMATION PROVIDED BY ANY INTERESTED BEFORE PARTY RENDERING ITS DECISION.

(G) THE DEPARTMENT OF COMMUNITY HEALTH'S DECISION SHALL BE PUBLISHED FOR PUBLIC COMMENT FOR A PERIOD OF NOT LESS THAN 30 DAYS. THE EFFECTIVE DATE OF THE DECISION SHALL NOT BE PRIOR TO THE CLOSE OF THE COMMENT PERIOD AND EFFECTIVE NOTICE OF THE DECISION'S FINALITY IS AVAILABLE TO PRESCRIBERS.

(3) NOTWITHSTANDING ANY OTHER PROVISION OF SECTIONS 111*l* TO 111R, UNLESS A DRUG HAS BEEN APPROVED OR HAD ANY OF ITS PARTICULAR USES APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION UNDER A PRIORITY REVIEW CLASSIFICATION, THAT DRUG SHALL NOT BE RECOMMENDED TO REQUIRE PRIOR AUTHORIZATION BY THE COMMITTEE

AND PLACED ON PRIOR AUTHORIZATION BY THE DEPARTMENT OF COMMUNITY HEALTH.

(4) THE COMMITTEE SHALL DEVELOP A GRIEVANCE MECHANISM FOR INTERESTED PARTIES TO APPEAL THE DEPARTMENT OF COMMUNITY HEALTH'S DECISION TO PLACE A DRUG ON PRIOR AUTHORIZATION. AFTER PARTICIPATING IN THE GRIEVANCE MECHANISM DEVELOPED BY THE COMMITTEE, ANY INTERESTED PARTY AGGRIEVED BY THE PLACEMENT OF A DRUG ON PRIOR AUTHORIZATION IS ENTITLED TO AN ADMINISTRATIVE HEARING BEFORE THE DEPARTMENT OF COMMUNITY HEALTH ACCORDING TO THE PROVISIONS OF THE ADMINISTRATIVE PROCEDURES ACT OF 1969, 1969 PA 306, MCL 24.201 TO 24.328.

(5) THE COMMITTEE SHALL REVIEW THE PRIOR AUTHORIZATION STATUS OF A DRUG EVERY 6 MONTHS.

(6) THE COMMITTEE SHALL PROVIDE 30 DAYS' PUBLIC NOTICE PRIOR TO EACH MEETING DETERMINING IF CHANGES SHOULD BE MADE TO THE DRUG PRIOR AUTHORIZATION REVIEW PROCESS.