THE SENATE
TWENTY-FIFTH LEGISLATURE, 2010
STATE OF HAWAII

S.B. NO. 2810

JAN 2 5 2010

A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUGS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Chapter 461, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"PART . MEDICATION THERAPY MANAGEMENT

§461-A Definitions. As used in this part, unless the context requires otherwise:

"Collaborative pharmacy practice" is that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol whereby the pharmacist may perform certain patient care functions authorized by the practitioner or practitioners under certain specified conditions or limitations.

"Collaborative pharmacy practice agreement" is a written and signed agreement between one or more pharmacists and one or more practitioners that provides for collaborative pharmacy practice for the purpose of conducting medication therapy management activities, as defined by law and the rules of the board.

"Medication therapy" means the treatment of disease or disorder through the use of prescription or non-prescription medications.

"Protected health information" means any information related to a person's health status or consumption of health care services that is protected from public disclosure by federal or state law.

"Qualified patient" means an individual who has prescription drug coverage through QUEST or medicare part D or who participates in the Rx plus program established pursuant to chapter 346.

§461-B Capacity for medication therapy management required. (a) Each pharmacy in the State that provides pharmacy services to qualified patients shall maintain the capacity to offer medication therapy management services pursuant to this part.

(b) A pharmacy shall meet the requirements of subsection (a) if the pharmacy employs at least one registered pharmacist who is party to a collaborative agreement allowing the pharmacist to provide medication therapy management and that pharmacist is present and available to provide medication management services on at least a half-time basis.

(c) A remote dispensing pharmacy operating pursuant to section 461-10.5 shall meet the requirements of subsection (a) if its responsible pharmacy meets the requirements of subsection (a) and a qualified patient has access to medication therapy management services through the video component required by section 461-10.5(h)(5).

§461-C Notice of availability. Each qualified patient shall be made aware of the availability of medication therapy management services:

(1) Verbally, each time the qualified patient receives a prescription that is covered by QUEST, medicare part D, or Rx plus from a pharmacy;

(2) In writing via a notice that complies with requirements specified by the board pursuant to section 461-G; and

(3) By posting of notice that complies with requirements specified by the board pursuant to section 461-G.

§461-D Scope of service. (a) Medication therapy management is a distinct service or group of services with the goal of optimizing therapeutic outcomes for individual patients and is independent of, but can occur in conjunction with, the provision of a medication or a medical device. Medication

therapy management encompasses a broad range of professional activities and responsibilities within the registered pharmacist's scope of practice. These services may include, but are not limited to, the following, according to the individual needs of the qualified patient:

(1) Performing or obtaining necessary assessments of the qualified patient's health status;

(2) Formulating a medication treatment plan;

(3) Selecting, initiating, modifying, or administering medication therapy;

(4) Monitoring and evaluating the qualified patient's response to medication therapy, including assessment of safety and effectiveness of individual medications;

(5) Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems including adverse events;

(6) Documenting the care delivered and communicating essential information to the qualified patient's other care providers as authorized by the qualified patient;

(7) Providing verbal education and training designed to enhance the qualified patient's understanding and appropriate use of medications;

(8) Providing information, support services, and resources designed to enhance the qualified patient's adherence to therapeutic regimens; and

(9) Coordinating and integrating medication therapy management services within the broader health care management services being provided to the qualified patient.

(b) Medication therapy management shall include a review of the qualified patient's medical records and each prescription drug that the qualified patient regularly or currently takes to identify:

(1) Known allergies;

(2) Rational therapy contraindications;

(3) Reasonable dose, duration of use, and route of administration of medications, considering the qualified patient's age, gender, and other patient factors;

(4) Reasonable directions for use of each medication that the qualified patient takes;

(5) Potential or actual adverse drug reactions;

(6) Drug-drug interactions;

(7) Drug-food interactions;

(8) Drug-disease contraindications;

(9) Duplications or redundancy among drugs or therapies that are part of the qualified patient's medication therapy;

(10) Proper utilization of medication therapy, avoidance of over- or under-utilization of medication therapy, and optimum therapeutic outcomes; and

(11) Abuse or misuse of medication therapy.

Upon recognizing any of the above, a pharmacist shall take appropriate steps to avoid or resolve the problem which may include consultation with the qualified patient's health care providers.

(c) At the time that a qualified patient who receives medication therapy management services begins taking a new prescription medication for the first time, the pharmacist providing medication therapy management shall review the qualified patient's record and provide patient counseling regarding the therapeutic use of the new medication and the interaction of the new drug with the qualified patient's existing medication therapy. Counseling pursuant to this subsection shall include:

(1) The brand name, generic name, if applicable, and an accurate description of the medication;

(2) The prescribed dosage form, dose, route of administration, and duration of the medication therapy;

(3) The intended use of the medication and its expected action;

(4) Special directions and precautions for preparation, administration, and use of the medication by the qualified patient;

(5) Common severe side effects, adverse effects, interactions, and therapeutic contraindications that may be encountered, means of avoiding any adverse effects, and the action required if they occur;

(6) Techniques for self-monitoring medication therapy;

(7) Proper storage and appropriate disposal of unwanted or unused medication;

(8) Prescription refill information;

(9) Action to be taken in the event of a missed dose; and

(10) Pharmacist comments relevant to the medication therapy, including any other information peculiar to the specific qualified patient or medication.

(d) Alternative forms of patient information such as written information leaflets, pictogram labels, or informational videos, shall be used to supplement medication therapy management when appropriate. A pharmacist who uses alternative information media pursuant to this subsection shall use the pharmacist's professional knowledge and clinical judgment in choosing which alternative forms of information to use.

(e) A pharmacist shall not provide medication therapy management pursuant to this chapter for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer medication therapy, except at the request of the hospital or institution and with the consent of the qualified patient.

(f) A pharmacist shall not provide medication therapy management to a qualified patient if the patient refuses the service.

§461-E Patient records. (a) A patient record system that meets the criteria established by section 328-17.7 shall be maintained by all pharmacies for qualified patients who receive medication therapy management services. The patient record system shall provide for the immediate retrieval of information necessary for a pharmacist to provide medication therapy

management and shall be created and stored in a manner that protects against unlawful use or disclosure of protected health information.

(b) A patient record maintained pursuant to this section shall include:

(1) The qualified patient's full name;

(2) The qualified patient's street address and telephone number;

(3) The qualified patient's age or date of birth;

(4) The qualified patient's sex;

(5) A list of all prescription drugs obtained by the qualified patient at a pharmacy within this State in the past two years;

(6) The qualified patient's known allergies and prior adverse drug reactions; provided that any adverse drug reactions that occur within the course of medication therapy management shall be immediately documented in the patient record;

(7) All chronic diseases, disorders, or conditions of the patient;

(8) The names of any nonprescription drugs, supplements, or other similar substances currently or regularly taken by the qualified patient;

(9) Pharmacist comments relevant to the individual's medication therapy management; and

(10) A copy of the collaborative pharmacy practice agreement required under section 461-F.

(c) Documentation of activities undertaken by a pharmacist in the course of medication therapy management shall be kept as part of the patient record and shall be readily available to other health care professionals providing care to the qualified patient upon specific authorization by the qualified patient to disclose the information. Documentation recorded or kept pursuant to this section shall be considered protected health information.

(d) Protected health information contained in a patient record may be used or disclosed only as allowed under this section, section 461-F, and relevant federal and state law.

§461-F Collaborative pharmacy practice agreement. (a) A pharmacist who provides medication therapy management shall have on file at the pharmacist's place of practice a written collaborative pharmacy practice agreement for each qualified

patient for whom the pharmacist provides medication therapy management. Parties to the agreement shall be the pharmacist who provides medication therapy management and the qualified patient's primary care physician. If a qualified patient does not have a designated primary care physician, any physician or advanced practice nurse practitioner with prescription authority who has ordered a prescription for the qualified patient may be party to the agreement.

(b) A collaborative pharmacy practice agreement shall allow a pharmacist, acting within the scope of the pharmacist's license to practice pharmacy, to conduct medication therapy management activities specified in the collaborative pharmacy practice agreement.

(c) A collaborative pharmacy practice agreement shall include:

(1) Identification of the pharmacist and practitioners who are parties to the agreement;

(2) The types of medication therapy management actions that the pharmacist may undertake, which may include:

(A) A description of the medical conditions experienced by the qualified patient, medications or categories of medications prescribed to the

qualified patient, and the activities that the pharmacist may take regarding each condition or medication;

(B) A description of the methods, procedures, decision criteria, and plan the pharmacist shall follow when conducting allowed activities; and

(C) A description of the activities the pharmacist shall follow, including documentation of decisions made, a plan for communication and reporting to the practitioner, and specifications for record keeping;

(3) A method for the practitioner to monitor clinical outcomes and compliance with the agreement and specifications as to when it shall be necessary for the provider to intercede;

(4) A description of the method that a provider shall use to evaluate effectiveness of patient care and ensure positive patient outcomes;

(5) A provision that allows the practitioner to override a medication therapy decision made by the pharmacist if the physician deems it necessary or appropriate;

(6) A provision that requires the pharmacist to report any adverse drug reaction to the provider in writing, immediately upon the pharmacist learning of an adverse reaction;

(7) A provision that allows either party to cancel the agreement by written notification;

(8) An effective date;

(9) Signatures of all collaborating pharmacists and practitioners who are party to the agreement; and

(10) Signed authorization by the qualified patient allowing the pharmacists and physicians who are party to the agreement to use and to disclose the qualified patient's protected health information to each other to the extent necessary to effectively participate in medication therapy management and to disclose the qualified patient's protected health information to any other practitioners as authorized by the qualified patient.

(d) Amendments to a collaborative pharmacy practice agreement shall be documented, signed by the pharmacist and physician, and dated.

(e) A collaborative pharmacy practice agreement pursuant to this section shall be reviewed, renewed, and revised as necessary at least once every year.

(f) A collaborative pharmacy practice agreement may be a standardized document or a checklist-type form developed by the physician, the pharmacist, or the board; provided that the collective pharmacy practice agreement meets all of the requirements of this section.

§461-G Rules. The board shall adopt rules pursuant to chapter 91 to effectuate the purposes of this part."

SECTION 2. Chapter 461, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§461- Electronic prescriptions; capacity required.** Every pharmacy and remote dispensing pharmacy operating under a permit or prior notification issued pursuant to this chapter shall have the capacity to maintain prescription records electronically and to accept and transmit prescription information electronically in accordance with the requirements of sections 328-17.7 and 328-17.8."

SECTION 3. Section 328-17.7, Hawaii Revised Statutes, is amended by amending subsections (b) and (c) to read as follows:

(b) Prescription records [~~may~~] shall be electronically maintained using an appropriate prescription information processing system; provided that:

(1) There [~~are~~] shall be procedures to maintain the records, including but not limited to auxiliary procedures for backing up files, computer downtime, and the protection of patient confidentiality; and

(2) Upon request the prescription records, or a subset thereof, shall be provided to the director or the director's agent, in a form specified by the director, within forty-eight hours.

(c) Prescription records shall be maintained electronically [~~or manually~~] such that the information contained in the records is readily retrievable during the pharmacy's normal operating hours."

SECTION 4. Section 346-1, Hawaii Revised Statutes, is amended by adding a new definition to be appropriately inserted and to read as follows:

""Medication therapy management" means the services provided to an individual by a pharmacist pursuant to part of chapter 461."

SECTION 5. Section 346-59, Hawaii Revised Statutes, is amended by amending subsection (b) to read as follows:

"(b) Rates of payment to providers of medical care who are individual practitioners, including doctors of medicine, dentists, podiatrists, psychologists, osteopaths, optometrists, pharmacists, and other individuals providing services, shall be based upon the Hawaii medicaid fee schedule. The amounts paid shall not exceed the maximum permitted to be paid individual practitioners or other individuals under federal law and regulation, the medicare fee schedule for the current year, the state limits as provided in the appropriation act, or the provider's billed amount.

The appropriation act shall indicate the percentage of the medicare fee schedule for the year 2000 to be used as the basis for establishing the Hawaii medicaid fee schedule. For any subsequent adjustments to the fee schedule, the legislature shall specify the extent of the adjustment in the appropriation act."

SECTION 6. Section 346-312, Hawaii Revised Statutes, is amended by amending subsection (b) to read as follows:

"(b) The program shall use manufacturer rebates, [~~and~~] pharmacy discounts, and medication therapy management to reduce prescription drug prices."

SECTION 7. Section 346-317, Hawaii Revised Statutes, is amended by amending subsections (a) and (b) to read as follows:

"(a) A pharmacy shall submit claims to the department to verify the amount charged to program participants. On a schedule to be determined by the department, the department shall reimburse each pharmacy for the discounts of prescription drugs and for medication therapy management provided to program participants.

(b) The department shall collect pharmacy use data necessary to calculate the amount of the manufacturer rebate under section 346-314[~~.~~] and the cost-savings realized due to medication therapy management. The department shall protect the confidentiality of information received as required under state or federal law, rule, or regulation."

SECTION 8. Section 346-318, Hawaii Revised Statutes, is amended by amending subsection (b) to read as follows:

"(b) Moneys in the Rx plus special fund shall be used for the following purposes:

(1) Reimbursement payments to participating pharmacies for discounts provided to program participants;

(2) The cost of administering the Rx plus program, including salary and benefits of employees, computer costs, and contracted services as provided in section 346-312; [~~and~~]

(3) The cost of providing medication therapy management to qualified patients under chapter 461; and

[~~(3)~~] (4) Any other purpose deemed necessary by the department for the purpose of operating and administering the Rx plus program.

All interest on special fund balances shall accrue to the special fund. Upon dissolution of the Rx plus special fund, any unencumbered moneys in the fund shall lapse to the credit of the general fund."

SECTION 9. Section 346-319, Hawaii Revised Statutes, is amended to read as follows:

"**§346-319 Annual report.** The department shall report the enrollment and financial status of the Rx plus program and information regarding any cost savings realized by implementing medication therapy management to the legislature no later than

twenty days prior to the convening of each regular session, beginning with the 2005 regular session."

SECTION 10. Chapter 461, Hawaii Revised Statutes, is amended by designating sections 461-1 to 461-22 as part I, entitled "General Provisions".

SECTION 11. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 12. This Act shall take effect on July 1, 2010.

INTRODUCED BY: _____

Report Title:
Medication Therapy Management; QUEST; Rx Plus; Medicare Part D

Description:
Authorizes pharmacists to provide medication therapy management to qualified patients. Requires pharmacies to maintain prescription records and medication therapy management records electronically.

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