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Health care attorneys for health care providers

The Puzzle of Pharmacists as Providers: Fitting the Pieces Together to Cover Rural Communities

35th Annual Oregon Rural Health Conference

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Objectives

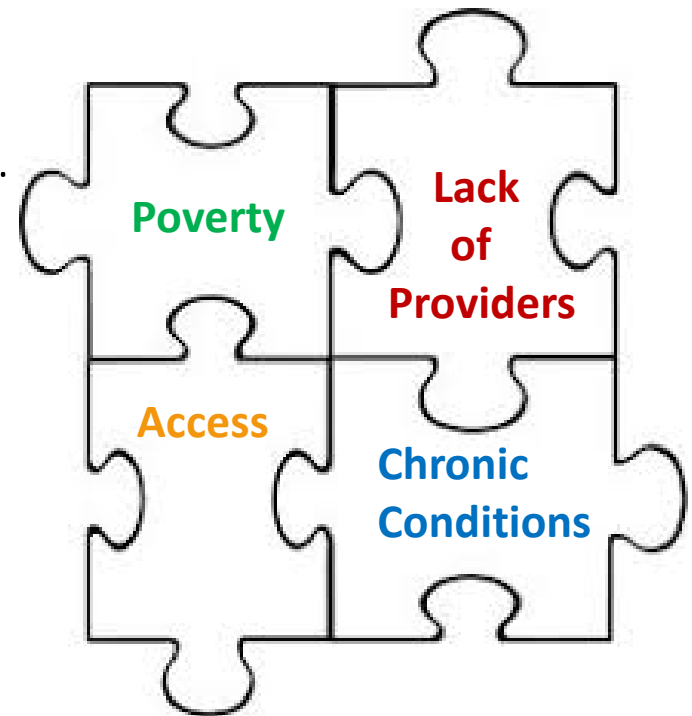
- Challenges in health care delivery in rural areas
- Challenges for pharmacists in rural areas
- Identify rural health-associated needs that could be met by pharmacists
 - Review the scope of expanding pharmacy practice in Oregon
 - Pharmacists as providers
 - Pharmacist collaborative practice
- Reimbursement for services



Health Care Delivery in Rural Areas in Oregon

- 19 rural and frontier service areas do not have a Patient Centered Primary Care Home (PCPCH) and the drive times for these areas can be as long as 78 minutes.
- There were 6 new PCPCHs in rural areas this year that had none last year.
- 9 rural primary care service areas have 0 FTE of primary care provider.
- 66 rural and frontier service areas have less than 0.5 mental health providers and 30 of those have 0 mental health providers.
- Oregon has an average Unmet Need Score of 46.2 out of 90. All but 2 of the service areas that fall under this mean are either rural or frontier.

-Oregon Areas Of Unmet Health Care Need Report. Oregon Office of Rural Health (August 2018)

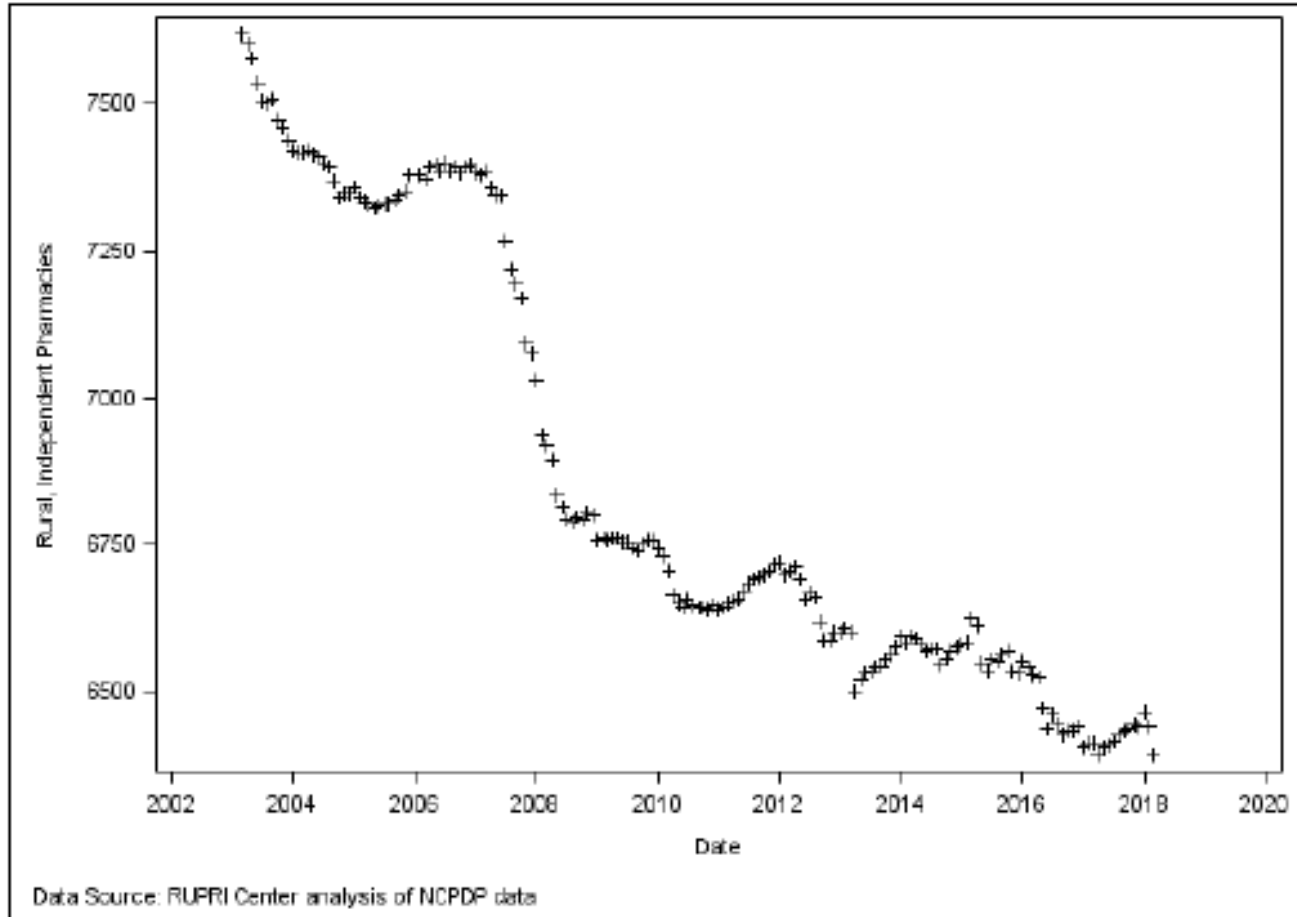


Challenges for Pharmacists in Rural Areas

- Over the last 16 years, 1,231 independently owned rural pharmacies (16.1%) in the United States have closed. The most drastic decline occurred between 2007 and 2009. This decline has continued through 2018, although at a slower rate.
- 630 rural communities that had at least one retail (independent, chain, or franchise) pharmacy in March 2003 had no retail pharmacy in March 2018.
- Closure of pharmacies in a rural area can have grave implications for the population's access to health services, requiring travel to another community or reliance on mail order services that cannot provide clinical services.

RUPRI Center for Rural Health Policy Analysis. *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018* (JULY 2018).

Monthly Count of Rural Independently Owned Pharmacies, 2003-2018



RUPRI Center for Rural Health Policy Analysis. Update: *Independently Owned Pharmacy Closures in Rural America, 2003-2018* (JULY 2018).

Number of Rural ZIP Codes, by State, Going from 1 or More Pharmacy to None, or from More than 1 to only 1, 2003-2018

	Mar 2003 – May 2009			Mar 2003 – Dec 2013			Mar 2003 – Mar 2018		
	1 to 0	>1 to 1	>1 to 0	1 to 0	>1 to 1	>1 to 0	1 to 0	>1 to 1	>1 to 0
OR	4	5	0	7	4	1	10	6	0
Total	359	195	10	471	256	19	589	302	41

RUPRI Center for Rural Health Policy Analysis. *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018* (JULY 2018).

Challenges for Pharmacists in Rural Areas

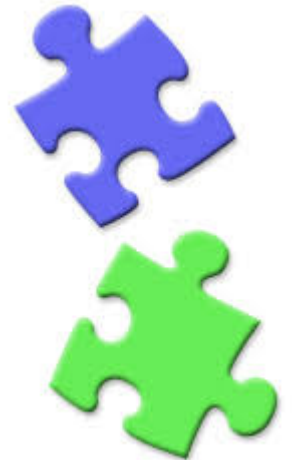
- Independent pharmacies tend to be more dependent on revenue from prescription medication sales, making them more vulnerable to increased competition and to decreases in reimbursement.
- Rural pharmacies typically pay more to drug manufacturers per prescription and sell a relatively low volume of medications.
- Increasing competition from mail-order and internet suppliers, who are able to sell at large volume and negotiate lower prices from drug manufacturers.
- Some third-party payers have low payment rates for prescription drugs, so pharmacies may actually lose money supplying medications paid for by these programs.

- See <https://www.ruralhealthinfo.org/topics/pharmacy-and-prescription-drugs>.

Role of Pharmacists in Rural Areas

- Rural pharmacies play an important role in alleviating the poor access to health services prevalent in many rural communities.
- In health professional shortage areas, pharmacists may act as first responders, providing clinical advice to include over-the-counter (OTC) relief that may aid in decreasing unnecessary emergency room visits for common conditions.
- The pharmacist's centralized placement in the community and clinical expertise are invaluable.
- Pharmacists provide an excellent source of human capital to the community by conducting primary prevention through health education.
- There are many functions of public health that can benefit from pharmacists' unique expertise that may include pharmacotherapy, access to care, and prevention services.
- Pharmacists are often involved in the clinical management of chronic diseases, and minor disease diagnosis and treatment.

-American Public Health Association. Policy Statement: The Role of the Pharmacist in Public Health (Nov 08, 2006).



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Advanced Journal list

Journal List > Pharm Pract (Granada) > v.14(4); Oct-Dec 2016 > PMC5184378

Pharmacy Practice
www.pharmacypractice.org

Pharm Pract (Granada). 2016 Oct-Dec; 14(4): 836.
Published online 2016 Dec 15. doi: [10.18549/PharmPract.2016.04.836](https://doi.org/10.18549/PharmPract.2016.04.836)

PMCID: PMC5184378
PMID: [28042356](https://pubmed.ncbi.nlm.nih.gov/28042356/)

Pharm

Assessment of pharmacists' delivery of public health services in rural and urban areas in Iowa and North Dakota

[David M. Scott](#), [Mark Strand](#), [Teri Udem](#), [Gabrielle Anderson](#), [Andrea Clarens](#), and [Xiyuan Liu](#)

- Pharmacists in rural areas reported higher frequency of delivery of some public health services:
 - Medication therapy management,
 - Immunizations,
 - Tobacco counseling, and
 - Medication take-back programs.
- Pharmacists in rural areas reported more frequent delivery of some essential services:
 - Evaluate the services the pharmacy provides,
 - Partner with the community to identify and help solve health problems, and
 - Conduct needs assessments to identify health risks in the community.

Expanding Role of Pharmacists

- Traditional Roles
 - Dispensing of prescription medications
 - Advising patients of OTC drug choice and use
 - Basic medication counseling
 - Distributing medicines and health supplies
 - Health education
- Expanding Roles
 - Pharmacist as provider
 - Clinical pharmacy practice



"Take one pill twice a day hidden in some cheese."

Pharmacists in Oregon Hold New Pieces of Practice

- Clinical pharmacy practice
 - Evaluation and management (E/M) services
 - Chronic care management
 - Review and order laboratory tests
 - Authority to order/change/discontinue prescription medications and laboratory orders
- Pharmacist as a provider
 - Immunizations
 - Prescriptive authority
 - Naloxone
 - Hormonal contraception
 - Prescribing of a compendia drug or device

Scope of Practice in Oregon

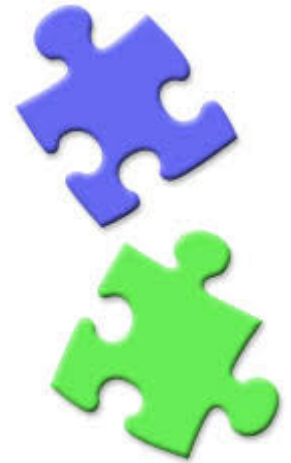
“Practice of clinical pharmacy” means:

- The health science discipline in which, in conjunction with the patient’s other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient’s health and wellness;
- The provision of patient care services, including but not limited to post-diagnostic disease state management services; and
- The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.

ORS 689.005 (30).

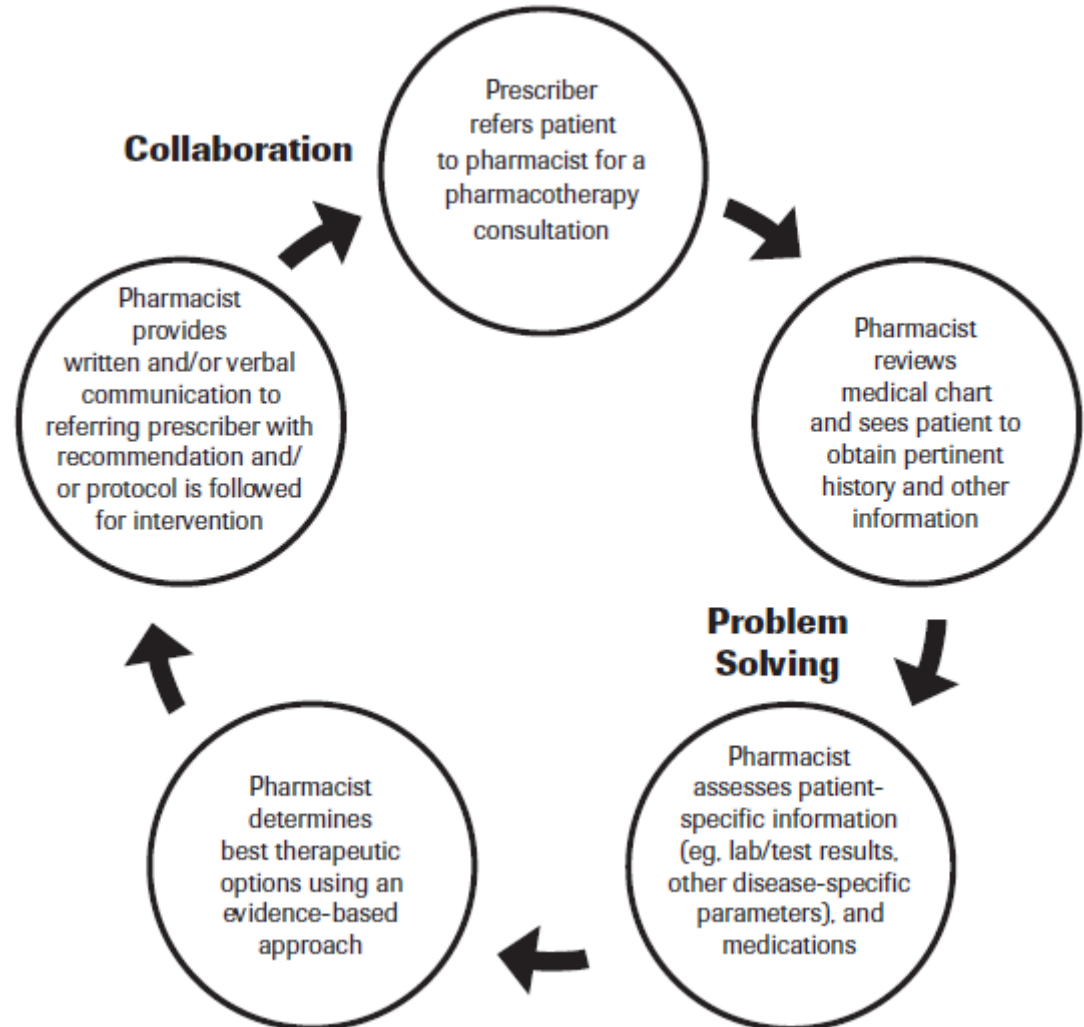
Clinical Pharmacy Agreement

- “Clinical Pharmacy Agreement” means an agreement between a pharmacist or pharmacy and a health care organization or a physician that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician. OAR 855-006-0005(3).



Clinical Pharmacy Agreements

- Formal agreement in which a licensed provider makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions

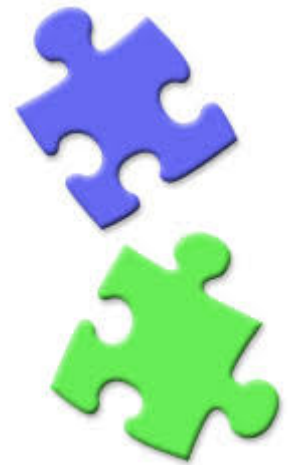


Source: Resource Paper of the Council on Credentialing in Pharmacy (February 2009).



Clinical Pharmacy Agreements

- Permits a pharmacist, in collaboration with the physician, to:
 - Perform patient assessment;
 - Initiate, adjust or discontinue drug therapy;
 - Order, interpret and monitor laboratory tests;
 - Formulate clinical assessments;
 - Develop therapeutic plans;
 - Provide care coordination for wellness and prevention of disease; and
 - Conduct essential patient education.



Clinical Pharmacy Agreements

Services provided by a clinical pharmacist:

- Review the patient's history of medications, hospitalizations, and recent provider visits.
- Assess the patient's social history, smoking, recreational drug use, occupational status, mental health, health literacy, housing status.
- Review the patient's refill history and align refills so that patient's medications are filled at the same times and to encourage the minimum number of visits to the pharmacy.
- Drug interaction analysis on patient's medication regimen using at least two different clinically sound and evidence based software programs.
- Prescription medications- pharmacist will start medications in accordance with established algorithms.
- Non-prescription medications--Pharmacist will review patient history, lab values, and drug interactions prior to recommending any over the counter products.
- Review and order laboratory tests.
- Authority to order/change/discontinue prescription medications and laboratory orders.

State Drug Therapy Management Protocols. OAR 855-019-0264.

- A pharmacist may participate in statewide drug therapy management protocols developed by the Oregon Health Authority to provide approved patient care services including but not limited to:
 - (a) Smoking cessation therapy;
 - (b) Travel health services; and
 - (c) Immunizations.

Collaborative Drug Therapy Management. OAR 855-019-0260

- Collaborative Drug Therapy Management (CDTM) means the participation by a practitioner and a pharmacist in the management of drug therapy pursuant to a written agreement that includes information on the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:
 - Between one or more practitioners in a single organized medical group and one or more pharmacists.
 - Agreements may include:
 - A detailed description of the types of diseases, drugs, or drug categories involved, and the activities allowed in each case;
 - A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities;
 - A detailed description of the activities the pharmacist is to follow including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the practitioner concerning specific decisions made. In addition to the agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;
 - Circumstances which will cause the pharmacist to initiate communication with the practitioner, including but not limited to the need for a new prescription order and a report of a patient's therapeutic response or any adverse effect.

PROPOSED RULEMAKING. OAR 855-020-0300.

Protocol Compendium

A pharmacist may prescribe, via drug therapy management protocol and according to regulations outlined in this Division, an FDA-approved drug and device listed in the following compendium:

(1) Continuation of therapy

- (a) A pharmacist may prescribe any non-controlled medication to extend a patient's prescription therapy to avoid interruption of treatment; and
- (b) In such cases, a pharmacist shall only prescribe a drug quantity sufficient for the circumstances, not to exceed a 60 day supply, and no more than two extensions in a 12 month period per medication.

(2) Conditions

- (a) Cough and cold symptom management
 - (A) Pseudoephedrine products for patients 18 years of age and older,
 - (B) Benzonatate, for the treatment of cough,
 - (C) Short-acting beta agonists,
 - (D) Intranasal corticosteroids.
- (b) Emergency Contraception, not including abortifacients.



PROPOSED RULEMAKING. OAR 855-020-0110.

Prescribing Practices

- A pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on the Formulary / Protocol Compendia
- The pharmacist must document the following, which constitutes the Visit Summary:
 - Create, approve, and maintain a drug therapy management
 - Collect subjective and objective information about the patient's health history and clinical status. Must be face-to-face, in-person; and
 - Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the pharmacist's established drug therapy management protocol; and
 - Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and
 - Provide notification, preferably via an interoperable information technology system, to the patient's identified primary care provider or other care providers when applicable, within five business days following the prescribing of a compendia drug or device.

Scope of Practice in Oregon

“Practice of pharmacy” means:

- The interpretation and evaluation of prescription orders;
- The compounding, dispensing and labeling of drugs and devices, except labeling by a manufacturer, packer or distributor of nonprescription drugs and commercially packaged legend drugs and devices;
- The prescribing and administering of vaccines and immunizations and the providing of patient care services pursuant to ORS 689.645;
- The administering of drugs and devices to the extent permitted under ORS 689.655;
- The participation in drug selection and drug utilization reviews;
- The proper and safe storage of drugs and devices and the maintenance of proper records regarding the safe storage of drugs and devices;

Scope of Practice in Oregon (cont.)

- The responsibility for advising, where necessary or where regulated, of therapeutic values, content, hazards and use of drugs and devices;
- The monitoring of therapeutic response or adverse effect to drug therapy;
- The optimizing of drug therapy through the practice of clinical pharmacy;
- Patient care services, including medication therapy management and comprehensive medication review;
- The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy; and
- The prescribing and administering of injectable hormonal contraceptives and the prescribing and dispensing of self-administered hormonal contraceptives pursuant to ORS 689.689.

ORS 689.005 (31).

Administration of Vaccines by Pharmacists. OAR 855-019-0270.

- A pharmacist may administer vaccines to persons who are at least 7 years of age and to persons who are at least 3 years of age during a declared emergency.
- With a valid prescription, pharmacists may administer vaccine to a patient of any age.
- The pharmacist must complete a course of training approved by the Board, including injection site, and Cardiopulmonary Resuscitation (CPR).
- The vaccines are administered in accordance with an administration protocol written and approved by the Advisory Committee on Immunization Practices (ACIP).



Oregon Pharmacy Protocols for Immunization

Vaccine/biologic	Date of Last Revision
Guidelines for managing adverse events	July 2018
Adverse Events E-kit Checklist and Report Form	July 2018
Cholera	July 2018
Diphtheria and Tetanus Toxoids	July 2018
Haemophilus influenzae type b (Hib)	July 2018
Hepatitis A & Twinrix	Aug 2018
Hepatitis B & Twinrix	July 2018
Human papillomavirus vaccine (HPV 9)	July 2018
Influenza (IIV 2018-19)	Sep 2018 New!!
Influenza (LAIV 2018-19)	July 2018
Japanese Encephalitis	July 2018
Meningococcal A, C, W, Y	Sep 2018 New!!
Meningococcal B Outbreak Only	July 2018
MMR/MMRV	Sep 2018 New!!
Mumps - Outbreak Only	July 2018
Pneumococcal Vaccines	July 2018
Polio	Sep 2018 New!!
Polio for Travelers	July 2018
Rabies (inactivated)	July 2018
Shingrix	July 2018
Typhoid	July 2018
Varicella-containing vaccines	July 2018
Yellow fever	July 2018

Prescribing: Naloxone - Delivery of Care. OAR 855-019-0460.

- (1) A pharmacist can prescribe naloxone and the necessary medical supplies for opiate overdose training.
- (2) A pharmacist can prescribe naloxone and the necessary medical supplies to an individual or entity seeking naloxone.
- (3) The pharmacist shall determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.
- (4) The pharmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.
- (5) The pharmacist shall dispense the naloxone product in a properly labeled container.
- (6) Naloxone may not be prescribed without offering to provide oral counseling to the authorized recipient, which may include dose, effectiveness, adverse effects, storage conditions, and safety....

Prescription and Administration or Dispensation of Certain Contraceptives. ORS 689.689.

- A pharmacist may prescribe and administer injectable hormonal contraceptives and prescribe and dispense self-administered hormonal contraceptives (including a patch or pill) to a person who is:
 - (a) At least 18 years of age; or
 - (b) Under 18 years of age, if the person has evidence of a previous prescription from a primary care practitioner or women's health care practitioner for an injectable hormonal contraceptive or a self-administered hormonal contraceptive.
- The pharmacist should administer the injectable hormonal contraceptive or dispense the self-administered hormonal contraceptive to the patient as soon as practicable after the pharmacist issues the prescription.

Contraceptive – Procedural Mandates. OAR 855-019-0425.

- A pharmacist must
 - Complete a training program approved by the State Board of Pharmacy that is related to prescribing injectable hormonal contraceptives and self-administered hormonal contraceptives;
 - Provide a self-screening risk assessment tool that the patient must use prior to prescribing the contraceptive;
 - Utilize and follow the Oregon Standard Procedures Algorithm to perform a patient assessment and prescribe contraceptives if clinically appropriate;
 - Refer the patient to the patient's primary care practitioner or women's health care practitioner upon prescribing and administering the injectable hormonal contraceptive or prescribing and dispensing the self-administered hormonal contraceptive;
 - Provide the patient with a written a Visit Summary; and
 - Advise the patient to consult with a primary care practitioner or women's health care practitioner....

Prescribing of a Compendia Drug or Device

- ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare".
- Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes.
- ORS 689.645 and ORS 689.649 require the Board to adopt rules to implement pharmacist prescriptive authority for items recommended by the Public Health and Pharmacy Formulary Advisory Committee to the Board to adopt for the Formulary and Protocol Compendia.
 - Oregon licensed pharmacist, practicing in Oregon, and performing a patient assessment via a face-to-face, in-person interaction
 - Includes drugs and devices

PROPOSED RULEMAKING. OAR 855-020-0200.

Formulary Compendium

A pharmacist may prescribe, according to regulations outlined in this Division, an FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented on the Visit Summary.

- (1) Devices and supplies
 - (a) Diabetic blood sugar testing supplies;
 - (b) Pen needles;
 - (c) Syringes;
 - (d) Nebulizers and associated supplies;
 - (e) Inhalation spacers;
 - (f) Peak flow meters;
 - (g) International Normalized Ratio testing supplies;
 - (h) Enteral nutrition supplies; and
 - (i) Ostomy products and supplies.
- (2) Medications (placeholder)

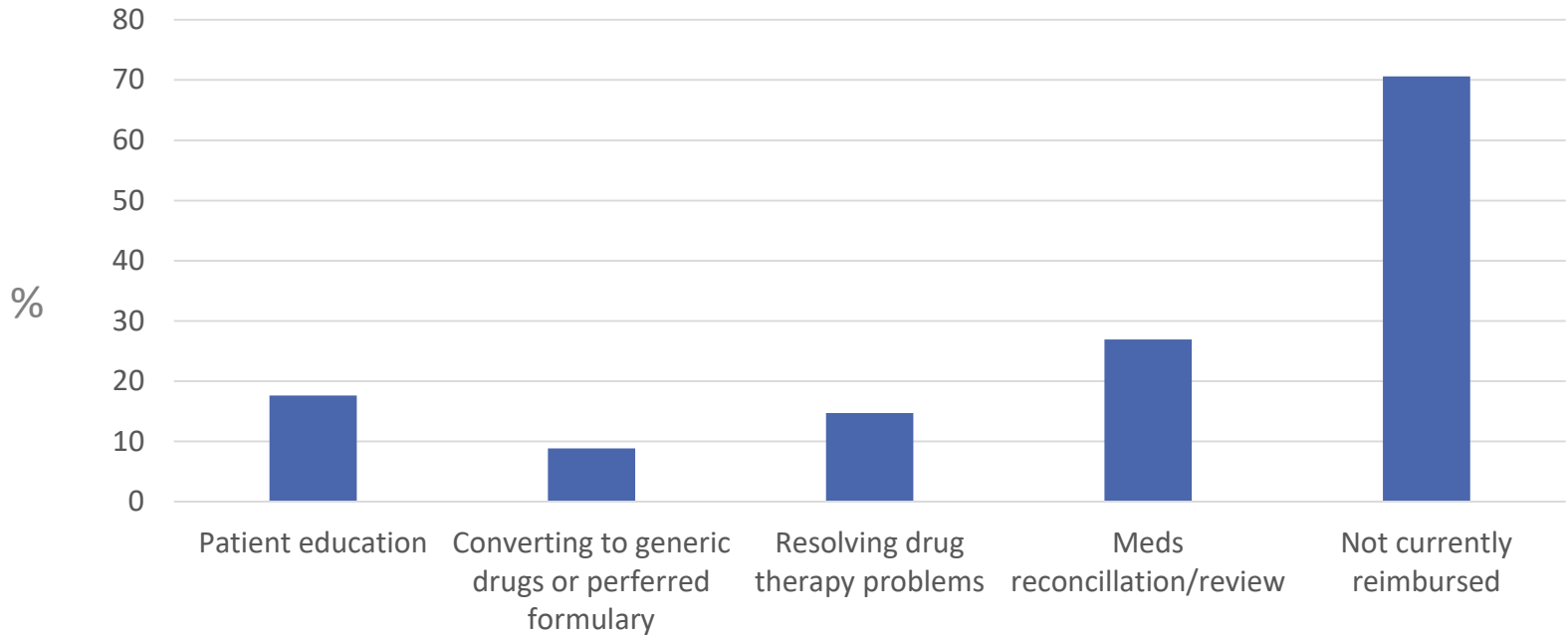


PROPOSED RULEMAKING. OAR 55-019-0200.

General Responsibilities of a Pharmacist

- Activities that require the professional judgment of a pharmacist include, but are not limited to:
 - (a) Drug Utilization Review;
 - (b) Counseling;
 - (c) Drug Regimen Review;
 - (d) Medication Therapy Management;
 - (e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;
 - (f) Practice pursuant to State Drug Therapy Management Protocols;
 - (g) Prescribing a drug or device, as authorized by statute;
 - (h) Ordering, interpreting and monitoring of a laboratory test;
 - (i) Oral receipt or transfer of a prescription; and
 - (j) Final verification of the work performed by those under their supervision.

Reimbursable Pharmacist's Tasks



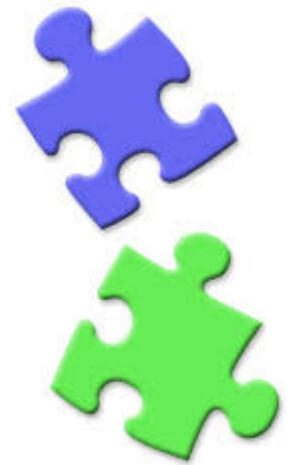
HIN Medication Adherence Survey January 2010.

Reimbursement: Private Insurance Carriers

- Some private insurance carriers have created a process for pharmacists to bill patients' medical insurance
 - Pharmacist enrolls in health plan provider networks
 - Pharmacists may bill for services provided within their scope of practice for covered patient care services under the plan.
 - Credentialing process for each plan
- Payments may be folded into a capitated payment model
- Payments may be associated with pay for performance incentives
- If not covered, pharmacists may charge patients a fee for the service.
- Oregon legislation does not address insurance coverage for pharmacist provider services, except
 - All state and federal laws governing insurance coverage of contraceptive drugs, devices, products and services shall apply to injectable hormonal contraceptives and self-administered hormonal contraceptives prescribed by a pharmacist. ORS 689.689(3).

Reimbursement: Medicare and Medicaid

- Medicare Part B
 - Pharmacists are not recognized Medicare Part B providers except when providing certain immunizations.
 - Physician's may delegate certain services to pharmacists furnished "incident to the physician's professional service".
- Medicaid
 - Pharmacists who administer vaccines or prescribe birth control to Oregon Health Plan (OHP) members must enroll with OHP as pharmacist providers.
 - OHP officially paid the first pharmacist claim July 2017.
 - Pharmacists are recognized as providers by the Washington state health care authority (WAC 182-502-0002).



Move Towards National Expansion of Medicare Coverage

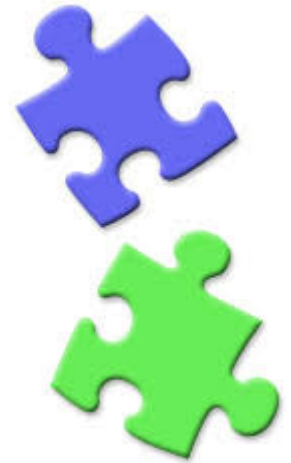
- Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592)
 - Purpose: To amend title XVIII of the Social Security Act to provide for coverage of pharmacist services under the Medicare program
 - Provision: Reimbursement under Medicare B for pharmacists providing services within their scope of practice in a health professional shortage area, medically underserved area, or medically underserved population

For Pharmacist to Bill Incident-to Under Medicare

1. Patient must first be seen by the physician for an evaluation or a Medicare covered service
2. Physician must have provided authorization for the service in the medical record(standard referral process)
3. Physician must continue to see the patient at a frequency that reflects active participation in the management of the course of treatment. Review of medical record alone does not qualify
4. Service provided by the pharmacist, is commonly furnished in a physician / Medicare Part B provider's office or clinic
5. The service must be medically appropriate to be given in the office/clinic

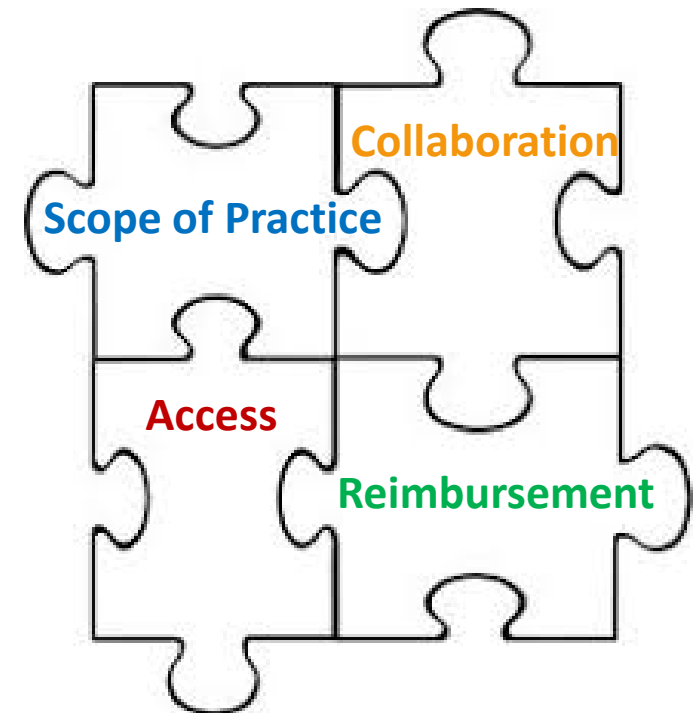
For Pharmacist to Bill Incident-to Under Medicare

6. Services must be within the pharmacist's scope of practice
7. Services must be furnished in accordance with applicable State law
8. A physician or practitioner must be on the premises, but not necessarily in the room
9. Pharmacist must be an employee, leased or contracted to the physician /provider



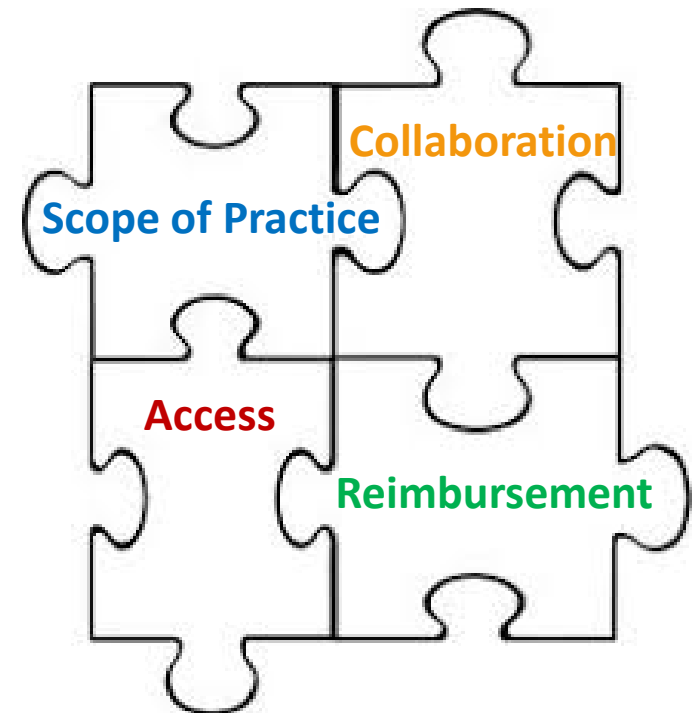
Pharmacists Role in Rural Health: Fitting the Pieces Together

- In rural areas, pharmacists not only provide access to medications but can also deliver clinical services:
 - Medication counseling,
 - Order/change/discontinue prescription medications,
 - Blood pressure and glucose monitoring,
 - Immunizations,
 - Evaluation and management (E/M) services,
 - Chronic care management,
 - Review and order laboratory tests,
 - Patient consultation,
 - Treatment of mild illnesses amenable to over-the-counter medications, and
 - Medication therapy management.



Pharmacists Role in Rural Health: Fitting the Pieces Together

- Pharmacist practicing as providers and clinical pharmacists in collaboration with physicians can expand patient access to primary care.
- Expanding roles of pharmacists in rural communities may bolster rural pharmacies.
- New practice models for rural pharmacists may include follow-up clinics, mobile clinics, and adding pharmacists into provider networks.
- Reimbursement for pharmacists' services is critical for their role in rural health.



Questions

This presentation is solely for educational purposes and is not intended as legal advice or as a substitute for the particularized advice of your own counsel and should not be relied upon as such, as the advice appropriate for you will be dependent upon the particular facts and circumstances of your situation. The transmission or receipt of this information, or the exchange of questions and answers, does not create an attorney-client relationship.

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Rachael A. Ream, J.D., Ph.D. has represented hospitals, physician groups, pharmacies, and other health care clients in strategic transactions, such as mergers and acquisitions, private equity transactions, joint ventures and physician contracting matters, including co-management arrangements, physician recruitment agreements, and employment and medical director agreements. Ms. Ream regularly assists clients with Medicaid audits, pharmacy audits, and responding to Statements of Deficiency. She also drafts and negotiates strategic supply management and equipment leasing and purchase agreements.

Ms. Ream represents clients on compliance matters, including defense of Medicare and Medicaid fraud and abuse cases, EMTALA, audits. She also advises clients regarding Anti-Kickback Statute and Stark Law compliance and HIPAA and HITECH compliance. She has experience conducting compliance risk assessments and GAP analyses, drafting compliance policies and procedures, and conducting compliance training.

Ms. Ream has extensive background in academic research and has represented clients in the area of research law, including negotiating Material Transfer Agreements, IRB Agreements, Clinical Trial Agreements, and the Common Rule. She earned a Ph.D. in Biological Sciences from Stanford University and completed a post-doctoral research fellowship in Biochemistry at Stanford University School of Medicine. Prior to graduating from Case Western Reserve University School of Law, Ms. Ream worked as a medical writer and editor in clinical research and helped clients prepare for FDA advisory panels.

Standards include

- 1) Education and competency,
- 2) Patient assessment, and determination of inclusion, exclusion and referral criteria
- 3) Collaboration with other healthcare providers, including mandated notification
- 4) Treatment and follow-up care planning,
- 5) Record-keeping, and
- 6) Prohibited practices.