Establishing Community-Based Public Health and Screening Services

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Primary Ingredients

- Establish the Interest
  - Personal and other pharmacists
  - Pharmacy staff
  - Pharmacy Management
- Recognized need
  - Patient care
  - Financial
- Willingness to take responsibility for care
  - Going the extra mile for you patients

- Expertise & planning
  - Don't reinvent the wheel
  - WSPA
- Startup money
  - Preparation/research time
  - Structural
  - Equipment-Rentals too.
- Space
  - Pharmacy Care Center
  - Private counseling room
  - HIPAA compliance

Primary Ingredients

- Time and workflow
  - Season Specific-Flu
  - Year-round
  - Efficient system= professional and cost effective
- Marketing & planning
  - Very important!!
  - Weakness of most pharmacists
- Equipment
  - Quality assurance
  - Documentation System
  - CDTA
  - CLIA

- Referrals
  - …from the 'big pond'
  - Partnerships
- Positive cash-flow
  - Essential to survival
  - Appropriate billing if applicable
- Dedication & growth
  - Give it some time and put effort into it

CLIA Waivers

Clinical Laboratory Improvement Amendment

- Established in 1988
- Comprehensive law that established standards to ensure accuracy and reliability of patient tests for all clinical laboratories in the United States

Laboratory

- Defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing diagnosis, prevention, treatment or assessment.

Types of Tests Regulated

- Urinalysis:
  - Dipstick glucose, protein
- General Chemistry:
  - Glucose
- Bacteriology
  - Strep
- Toxicology:
  - home test kits for opiates/methamphetamines

Types of Tests Regulated

- General Immunology:
  - Mono screen (whole blood)
- Hematology:
  - Protime/INR
- Virology:
  - Influenza

Evaluation of Tests

- Each test is evaluated based on 7 criteria:
  - Knowledge needed to perform test
  - Training is needed to run the test
  - Reagent and materials preparation
  - Calibration
  - Troubleshooting/equipment maintenance
  - Interpretation of results
  - Characteristics of operational steps

Evaluation of Tests

- The device or test in question is evaluated in each category and receives a score of 1, 2 or 3
- Tests or devices receiving a score of 1-12 are labeled as "Moderate Complexity"
- Test or devices receiving a score higher than 12 are labeled as "High Complexity"

3 Categories of Tests

- Waived
  - All home-use testing devices
    - Diabetes monitors
  - All OTC urine tests
    - Pregnancy/Ovulation
    - Protein/Ketones
- Moderate Complexity
  - Anticoagulation testing devices
- High Complexity

"Waived" Status

- Must be simple to use
- Must have insignificant risk of error
- Must be accurate
- Test should contain a failure alert mechanism to prevent erroneous results

Accuracy

- FDA interprets accuracy to mean in test performance and not analytical accuracy.
  - The test must perform the same in the hands of untrained users as it does in the hands of laboratory professionals

Insignificant Risk

- Pose no harm to the patient if the test is performed incorrectly

"Waived" Status

- By Regulation
- By petition by the manufacturer who provides scientifically valid data meeting waiver criteria
- Those tests approved for home use

Pharmacy Based Screenings

- Will utilize <u>waived blood</u> tests
  - Cholesterol Screening
  - Glucose Monitoring
- Some locations utilizing <u>waived urine</u> testing
  - Harborview Pharmacy Methadone Maintenance Project

Application for Certification

- Even if you are using waived tests only in your pharmacy you must obtain a <u>Certificate of Waiver</u> from the state in which the testing will be done.
  - Yes, even if you perform only 1 test a year!
  - Also known as a Medical Testing Site (MTS)

To Apply for a CLIA Waiver

http://www.cms.gov/clia/cliaapp.asp

CLIA requires all entities that perform even one test, including waived test on ... "materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain Federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program.

List of CLIA Waived Tests

- http://www.cms.hhs.gov/clia/waivetbl.pdf

Issues

- How should you characterize your program?
  - Screening only
  - Screening and management
  - Survive mostly on private-pay? Insurance?
  - Survive on sale of related products
  - Primarily educational, not disease management & therefore less threatening to physicians?

Issues

- Screen people at "health fairs" or pull high-risk patients from Rx profiles and make appointments?
- Both require careful planning and understanding of workflow issues
- Is the screening service covered by Medicare or Medicaid? Should you refer the screening someone else?

Issues

- One-on one screening and counseling only?
- Small group sessions?
- Large group sessions?
- Consider privacy vs. group assistance, costs per patient vs. income, space and time vs. staffing
- Consent forms? Retaining records? Where?

Issues

- Liability
- Concerns often prevent programs from being implemented (i.e MD feedback)
- Be prudent about asking higher-risk patients to take on new activities
- If risk is increased, is it worth it?

Issues

- What types of new relationships must pharmacists forge with patients, other healthcare providers, payers, employers, unions?
- Is your company interested in supporting your efforts?

Issues

- Is there a need for this service in the community?
- Are your services in the best interest of all?
  - Is random screening prudent? Focused screening?
  - Do you have the skills? Documentation? Quality assurance?
  - Are pharmacists an appropriate provider?

- How do you get paid?

Getting Paid…

HCFA = CMS

- CMS is the Centers for Medicare & Medicaid Services. Formerly known as the Health Care Financing Administration (HCFA).
- CMS is the federal agency responsible for administering
  - Medicaid and Medicare
  - SCHIP (State Children's Health Insurance)
  - HIPAA (Health Insurance Portability and Accountability Act)
  - CLIA (Clinical Laboratory Improvement Amendments)
  - and several other health-related programs.

Medicaid

- Medicaid is an assistance program. Medical bills are paid from federal, state and local tax funds. It serves low-income people of every age. Patients usually pay no part of costs for covered medical expenses. A small co-payment is sometimes required. Medicaid is a federal-state program. It varies from state to state. It is run by state and local governments within federal guidelines.

Wake up your neighbor

Medicaid Billing

- Each pharmacy will need a Medicaid billing number and pharmacies can use that number for product billing.

- These are already in place in all pharmacies that serve Medicaid patients

Medicaid Provider Number

- Emergency Contraception Billing on CMS 1500 for Consultation services
  - All pharmacists use # 977707
- Also used for OTC Barrier Contraceptive Billing.

Medicaid Billing Specifics for EC

- Counseling is service-related and so is billed on the CMS 1500 form
  - Diagnosis code: V25.09 (field 24E)
  - Prescribing provider: 9777707 (field 17A)
  - MAA procedure code: 4805A (field 24D)
  - Current maximum payable: 89% of $15 ($13.50)
- Bill appropriate Rx(s) in usual way online
- **Payments limited to pharmacies with EC CDTAs!**

National Provider Identifier (NPI)

- National Provider Identifier (NPI) for Medicare will eventually be used for Medicaid billing.
- More Later…

Medicaid Provider Status

- Yes, according to WAC 388-502-0010 Payment-Eligible Providers Defined
- Due to a letter sent by Rod Shafer on behalf of WSPA members in Sept 2000 recommending pharmacists be considered "eligible providers"
- No payment yet because there are no codes to bill for pharmacy services BUT it is a necessary step in the right direction.
- Not recognized at a national level yet….

Medicare

- Medicare is an insurance program. Medical bills are paid from trust funds which those covered have paid into. It serves people over 65 primarily, whatever their income; and serves younger disabled people and dialysis patients. Patients pay part of costs through deductibles for hospital and other costs. Small monthly premiums are required for non-hospital coverage. Medicare is a federal program. It is basically the same everywhere in the United States and is run by the Centers for Medicare & Medicaid Services, an agency of the federal government.

Medicare Fee-For-Service Provider/Supplier Enrollment

- Pharmacists should enroll as providers
  - Professional advantages: provider status recognized
  - Business side: must accept assignment if provider?
- Use CMS-855b form

Applying for Medicare Provider Number CMS-855

- www.cms.hhs.gov/providers/
  enrollment/forms/
  - Electronic or .pdf

Health Insurance Claim Form CMS-1500

- Universal billing claim forms
- Accepted by virtually all insurers
- Available hardcopy and electronically
- New OCR scanning system requires RED form.
- New STRICT writing requirements.
- Individual or Roster billing on this form

CMS's Healthcare Common Procedure Coding System

- A three level coding system, developed , updated and published by CMS.
  - Used to describe health care services provided to patients and
  - A basis for claims payment using the CMS-1500 form.

Level 1

- CPT codes (procedure codes)
  - Physicians' Current Procedural Terminology are codes that describe medical services and procedures. Adopted and implemented by CMS (HCFA) but published and copyrighted by the AMA.
  - The pharmaceutical equivalent of the NDC number.

CMS 855b

- You can't bill Medicare for covered services unless you are enrolled.
- To bill for immunizations:
  Fill in 1b,1d,2(if required), 5-9, 14, 15(if required), 17, and 18.

Bill Medicare for Immunizations

- Using CMS-1500 to bill the local carrier:
  - Codes:
    - Influenza 90657 Split virus 6-35 months
    - Influenza 90658 Split virus 3 years and above
    - Influenza 90659 Whole virus
      - Administration code: G0008
      - Diagnosis code: V04.8

Bill Medicare for Immunizations

- Pneumococcal 90732 polysaccharide vaccine, 23-valent, adult.
  - Administration code: G0009
  - Diagnosis code: V03.82

Medicare Provider Number
Mass Immunizers

- Pharmacists in the State of Washington CAN bill for immunizations from Medicare
  - As provider/supplier- Mass Immunizers
  - Only for Influenza, Pneumonia, and Hepatitis B
  - MUST accept assignment and bill if they are a provider

Roster Billing for Mass Immunizers

- Manual and electronic billing available
- Mass Immunizer
  - Agrees to accept assignment for influenza and pneumococcal vaccines
  - Bills Medicare for vaccines for multiple beneficiaries.

Roster Billing

- Roster must include:
  - Beneficiary's name
  - Address
  - Health Insurance Claim Number (HICN)
  - Date of Birth
  - Sex
  - Date of Service
  - Signature

Roster Billing continued

- Cannot bill both Influenza and Pneumococcal on same roster.
- Pneumococcal Submission Roster
  - WARNING: Ask beneficiaries if they have been vaccinated with PPV!
  - Rely on patients memory to determine prior vaccination status
  - If patients are uncertain whether they have been vaccinated within past 5 years, administer the vaccine
  - If patients are certain that they have been vaccinated within past 5 years, do not revaccinate.

CPT Code Types

- Evaluation and Management codes (E/M)

  - 99201: New patient; 5-10 minutes, minimal complexity
  - 99211: Established patient; 5-10 minutes, minimal complexity (often referred to as "incident to" billing code.
  - More Drug Therapy CPT codes being developed for MTMS

ICD-9-CM Codes
(Diagnosis codes)

- The International Classification of Diseases, 9th Revision, Clinical Modification
- It classifies diseases, injuries, and pt encounters
- Examples:
  - 493.0 Asthma, childhood
  - V04.8 flu vaccine (prevention of influenza)

- CMS 1500 form box 21

NPI Numbers

- National Provider Identifier
- "Universal" provider number
- Replaced UPIN number
- Needed for successful billing
- Indicates medical necessity and referral
- CMS 1500 form: Box 17-A
- Use physician's NPI for "incident to" billing.

Medicare Provider Status-National Finally….

- Starting May 23, 2005, ALL health care providers can apply for their National Provider Identifier (NPI).
- The NPI will replace health care provider identifiers in use today in standard health care transactions.
- The health plans with whom you do business will instruct you as to when you may begin using the NPI in standard transactions.
- All HIPAA covered entities except small health plans must begin using the NPI on May 23, 2007; small health plans have until May 23, 2008. For additional information, to complete an application, and to access educational tools, visit https://nppes.cms.hhs.gov on the web.

CMS Plans for Transitioning to the National Provider
Identifier (NPI) in the Fee-for Service Medicare Program

- Between May 23, 2005 and January 2, 2006, CMS claims processing systems will accept an existing legacy Medicare number and reject as unprocessable any claim that includes only an NPI.
- Beginning January 3, 2006, and through October 1, 2006, CMS systems will accept an existing legacy Medicare number **or** an NPI as long as it is accompanied by an existing legacy Medicare number.
- Beginning October 2, 2006, and through May 22, 2007, CMS systems will accept an existing legacy Medicare number **and/or** an NPI. This will allow for 6-7 months of provider testing before only an NPI will be accepted by the Medicare Program on May 23, 2007.
- Beginning May 23, 2007 CMS systems will **only** accept an NPI.

Moral to the story

- Billing may seem like a lot of work but the more common place it becomes, the closer we get to compensation for our services!!

Cholestech at Katterman's Pharmacy

Anticoagulation Clinic at the Polyclinic

**Health Maintenance Counseling
at Kelley-Ross Pharmacy**

Osteoanalyzer at Pharmacy Legislative Day

Pharmacy Legislative Day in Olympia

Resources

- WSPA Training and Rentals (425) 228-7171
- http://www.futrex.com
- http://www.cholestech.com
- http://www.norland.com   (OsteoAnalyzer)
- APhA, ASHP, NACDS, NCPA
- http://cms.hhs.gov/providers/edi/default.asp
- Manufacturers (funding, projects, literature)

Questions?

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