Retail Medicine
Shop Until You Drop

Washington State Society of Healthcare Attorneys
2016 Spring Health Law Conference
April 29, 2016

Adam Romney, Dipa Sudra & Caitlin Forsyth
Why Go Retail?

- Patient’s choice
- Transparency
- Affordable
- Personalization
- Marketing to patient, not provider
- Convenience

Consumers pushing for Healthcare Transformation
What is Retail Medicine?

[Logos of various retail medicine companies]
Follow the Numbers

$4.1 \text{ B} \quad \text{Health Funding Priorities in 2014}

Top 6

(1) Big health ($393 \text{ M})
(2) Healthcare consumer engagement ($323 \text{ M})
(3) Digital medical devices ($312 \text{ M})
(4) Telemedicine ($285 \text{ M})
(5) Personalized medicine ($268 \text{ M})
(6) Population health management ($225 \text{ M})

Source: Rock Health, "Digital Health Funding Tops 4.1 Billion - 2014 Year Review"
Today’s Agenda

Who can own?

Must the clinic be licensed?

Who can staff?

What services can be provided?

How to get paid?

Fraud and Abuse
Who Can OWN?

Providers
- Hospitals, Clinics or Other
- Provider’s Payor Contracts
- Government Program Enrollments

Lay Entity
- Corporate Practice of Medicine
- Enter PSAs with Providers
- Cannot unduly influence professional services

“Captive” Models
- Management Services Organization
- PC owned by physician
- Restrictive Covenants
The Retail Clinic’s Licensure Status?

- State laws can vary based on scope of services (e.g., surgical clinics, cardiac cath, imaging, etc., may have specific state clinic licensure requirements)

- Specific license category may exist for “retail clinic” model
  - Massachusetts: “Limited Service Clinic” license
    - LSC regulations apply to referrals to PCPs, limiting repeat customers, record keeping requirements, after hours coverage, supervision, etc.
  - Arizona: “Outpatient Treatment Centers”
  - Kentucky: “Minor Care Health Clinics”
Who Can Staff Retail Clinic?

- Typically staffed by the following (or any combination thereof):
  - Physicians
  - Physician assistants (PAs)
  - Nurse practitioners (NPs)
  - Other midlevel practitioners and personnel
- Physician oversight of NPs and PAs is governed by state law
Common Retail Clinic Staffing Questions

- What are the supervision requirements of non-physicians?
- Must there be constant physical presence of a physician?
- Are physicians only required to periodically review a nonphysicians work and charts?
- Can physicians supervise via telemedicine?
- Are non-physicians subject to clinical limitations?
- Are there limits to prescription writing?
Washington Answers to Staffing Questions

- **PAs** - supervision required (*delegation agreements*)
  - Under approved delegation agreements, PAs can prescribe, order, administer and dispense legend drugs and Schedule II-V controlled substances
  - Special rules for PAs working in remote sites
    - Medical Commission must approve

- **NPs** - no supervision required
  - NPs must obtain instruction, supervision, and consultation as necessary before implementing new or unfamiliar techniques or practices.
  - NPs must apply to the DOH for prescriptive authority, which permits them to prescribe, order, administer and dispense legend drugs and Schedule II-V controlled substances
Scope of Services in Retail Setting

- Can be limited by:
  - State clinic/facility licensure laws (*see above*)
  - Scope of practice of staff (*see above*)
  - State law and policy
    - Telemedicine
    - Direct Access
    - Supervision Rules
    - Consent and Standard of Care
  - Benefits Laws
WA: Scope of Practice of Telemedicine Services

- **Standard of Care.** Practitioners will be held to the **same standard of care** as practitioners engaging in traditional settings.

- **Practitioner-Patient Relationship.** The relationship is clearly established when the practitioner agrees to undertake diagnosis and/or treatment of the patient and the patient agrees that the practitioner will diagnose and/or treat, **whether or not there has been or is an in-person encounter between the parties.**
**Patient Evaluation.** The telemedicine provider must undertake a history and evaluation prior to the provision of telemedicine services. The provider must assess **whether the situation is appropriate** for telemedicine.

- Circumstances may require a surrogate examiner to be present with the patient to provide necessary in-person observations

**Allowable Treatment Parameters.** The telemedicine practitioner may provide **any treatment** deemed appropriate for the patient, including prescriptions, **if** the evaluation performed is adequate to justify the action taken.

**Prescriptions.** Exercise caution in prescribing **controlled substances**
Direct Access Lab Testing

- **Physician Order.** Washington labs may only accept orders for testing from “authorized persons” – not specifically defined
  - Many states only permit orders from healthcare practitioners

- **FDA.** Requires DTC testing providers to obtain FDA marketing approval prior to marketing “medical devices” to consumers
  - FDA characterizes these tests as medical devices because they are “intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body”
  - **Warning letters** sent to 23andMe, DNA4Life, DNA-CardioCheck, Inc., etc.

- **FTC.** Closely scrutinizes DTC testing providers’ **claims to consumers about the capabilities of testing and uses of test results**
WA: Direct Access to Physical and Occupational Therapy

- **PT.** WA does not require referrals for PT services except for electroneuromyographic examinations and wound care services (sharp debridement, dressings, topical agents, etc.)

- **OT.** Treatment by an OT (1) of a “medical case” or (2) with wound care management services may take place only upon the referral of a MD, DO, podiatric physician and surgeon, naturopath, chiropractor, PA psychologist, optometrist, or ARNP licensed in WA.
Other Scope of Service Considerations

- **Supervision of all staff and services**
  - “Failure to adequately supervise auxiliary staff” is unprofessional conduct in Washington
  - Are nurses, technicians and other personnel adequately trained and educated on use of medical devices, injections and diagnostic imaging tests?

- **Patient consent**
  - Has patient consented to the particulars of this retail setting?
  - States often require enhanced consent for telemedicine care

- **Standard of care**
  - Is the diagnosis or treatment appropriate for retail setting?
  - Will the patient understand the results?

- **Is there an emergency plan?**
Employer On-Site Clinics

- Benefits Issues: Acronym Soup
  - ERISA
  - COBRA
  - HDHP/HSA
  - ACA
**ERISA**

**GHP Definition:** a plan, fund, or program, established or maintained by an employer, for the purpose of providing certain benefits, **including medical, surgical or hospital care or benefits**, through the purchase of insurance or otherwise, to participants and beneficiaries

**Exemption:** facilities for the treatment of minor injuries or illness or rendering **first-aid** in cases of accidents occurring during working hours

Clinic offering preventive visits, diagnostics or regular check-ups likely an ERISA plan

---

**ERISA compliance – Bundling?**

<table>
<thead>
<tr>
<th>Plan documents/SPD/SMM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claims/appeals procedures</td>
</tr>
<tr>
<td>Form 5500/SAR</td>
</tr>
</tbody>
</table>
GHP Definition: A plan maintained by an employer to provide health care to individuals who have an employment-related connection to the employer or to their families

Limited exception: First aid provided only to current employees at no cost during the employer's working hours for treatment of a health condition, illness, or injury that occurs during those working hours

Issues

How to determine COBRA rate?

Any security/employee relations issues for former employees?
HSA Eligibility

Many ERs offering HDHP/HSA option

HSA eligibility – no coverage below the statutory minimum HDHP deductible

Therefore, retail medicine models potentially a problem....

...but there are some planning tools...
Insignificant benefits, e.g. physicals, immunizations, allergy shots, non-prescription pain killers

Permitted coverage, provided through insurance or otherwise, for accidents, disability, dental care, vision care or long-term care

Permissible preventive care benefits, such as annual physicals and screening services (see next slide)

Coverage with a deductible greater than or equal to the statutory minimum annual deductible. For 2016, $1,300 for self-only coverage and $2,600 for family coverage

EAP, disease management and wellness programs, so long as they do not provide significant medical benefits
Permitted Preventive Care Services

Preventive care includes:

• Periodic health evaluations
• Routine prenatal/well-child check
• Immunizations
• Tobacco-cessation and obesity weight-loss programs
• Screening devices
• Preventive services that must be provided without any cost-sharing under health care reform

Preventive care does not generally include any service or benefit intended to treat an existing illness, injury or condition. However:

• Treatment of the related condition is OK if unreasonable or impracticable to perform another procedure
• Incidental/ancillary treatment might be OK
## Other Planning Techniques

<table>
<thead>
<tr>
<th>Exclude HDHP enrollees</th>
<th>Often contrary to the purpose of retail medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Require FMV payment until statutory minimum deductible met</td>
<td>No IRS guidance</td>
</tr>
<tr>
<td></td>
<td>How to calculate FMV? Retail cost? Should you allocate the cost of running the clinic?</td>
</tr>
<tr>
<td>Receive permitted/preventive coverage only until deductible met, then receive full coverage</td>
<td></td>
</tr>
</tbody>
</table>
Affordable Care Act

- Retail clinics generally not a substitute for existing medical plans
- Cadillac tax?
  - 40% excise tax, effective 2020
  - Can retail clinics help ERs manage costs?
What Pays for Retail Medicine?

Is it a “Covered Service? If so....

<table>
<thead>
<tr>
<th>Medicare</th>
<th>Medicaid</th>
<th>Commercial</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Check conditions of payment</td>
<td>• Enrolled in the program?</td>
<td>• Are you contracted or out of network?</td>
</tr>
<tr>
<td>• Order required?</td>
<td>• State may consider you to be enrolled?</td>
<td>• State False Claims Law</td>
</tr>
<tr>
<td>• Limited practice settings?</td>
<td>• Medicaid Provider Agreements may require providers to bill program for covered services</td>
<td>• Compel coverage under Telemedicine Parity Law?</td>
</tr>
<tr>
<td>• Criteria in regs, manuals, NCDs or LCDs?</td>
<td>• Mandatory Claims Submission Law</td>
<td></td>
</tr>
<tr>
<td>• Mandatory Claims Submission Law</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
WA Medicaid: Telemedicine Coverage

- **Covered Services**
  - “The agency reimburses medically necessary covered services through telemedicine when the service is provided by a Washington Apple Health provider and is within their scope of practice.”

- **Non-Covered Services**
  - Email, audio only telephone, and facsimile transmissions
  - Installation or maintenance of any telecommunication devices or systems
  - Purchase, rental, or repair of telemedicine equipment

- **Location Requirements**
  - Patient must be located in an approved originating site (e.g., physician office, clinic, hospital/CAH, rural health clinic, school)
Can a Retail Clinic Bill a Medicare Patient?

Medicare Reimbursement Concepts

- Covered Benefit Categories
- Non-Covered Service
- Excluded Service
- Nonpayment due to Conditions of Payment

The Mandatory Claims Submission Law

Medicare Assignment/Limiting Charge Rules

Advance Beneficiary Notice Rules

“Substantially in Excess” rules and proper Discount Policies

Free Services and Beneficiary Inducements

Consistency with Fee Schedules or Chargemaster
Can a Retail Clinic Bill a WA Medicaid Patient?

- **Provider must:**
  - Verify whether patient is Medicaid-eligible
  - Accept Medicaid payment as “payment in full”

- **Provider **cannot bill** patients:**
  - If Provider has not complied with Conditions of Payment
  - Unless an “Agreement to Pay for Healthcare Services” Form HCA 13-879 is signed *before* service is furnished
  - Form required for services defined as “covered” or “noncovered” by WAC

- **Provider **can bill** patients:**
  - If patient refuses to complete HCA 13-879 forms
  - If patient represented himself/herself as a private pay client and not receiving medical assistance
  - For “excluded services” as defined by WAC
Retail Medicine / Fraud & Abuse “50 Shades of Gray”
Fraud & Abuse Issues

The Usual Suspects:

- Federal Laws
  - Federal Anti-Kickback
  - Stark Law
  - Civil Money Penalties Law
- State Laws
  - State Anti-Kickback
  - State Physician Self-Referral/Disclosure
  - Fee-Splitting
  - Patient Brokering
  - Consumer Protection
  - Internet Questionnaires
Launching Retail Medicine: “And you may ask yourself....”

- Who is the provider?
- What is the service?
- Which CPT codes?
- Which payors?
- Which regulators?
- Who markets?
- Which legal entities?
- Where do patients flow?
- Where does the money flow?
- Where does data flow?
Thank You!

A law firm devoted to helping our clients achieve success as they define it by providing service customized to their particular needs.

Davis Wright Tremaine Defining Success Together