

# Government Regulation in Health

Angela Fertig

Spring 2009

# Prospective Payment System

- ▶ Description
  - ▶ payment decided before care based on diagnosis
  - ▶ diagnosis categorized into 506 Diagnosis Related Groups (DRGs)
  - ▶ hospital must eat cost if costs more, keeps extra if costs less
- ▶ Creates incentive for firms with market power to lower costs
- ▶ Creates competitive situation because firm is price-taker not price-setter
  - ▶ Yardstick Competition: compete with self to hit target cost (below reimbursement)
- ▶ Difficult because it requires a lot of information—defining DRGs, getting average costs, etc.

## Effects of PPS

- ▶ avg length of hospital stay fell substantially
- ▶ access and quality of care may have decreased
- ▶ diagnosis assigned is more strategic
- ▶ less severe cases treated as outpatient
- ▶ profits of hospitals fell
- ▶ lowered costs

## Certificate of Need

- ▶ Description
  - ▶ prohibits building new hospital bed capacity and expensive equipment without govt approval
  - ▶ govt determines # beds/units geographic area needs and allows construction only if available supply does not meet that need
- ▶ Recall from before: Why restrict entry/competition? Doesn't more competition always help consumers?
  - ▶ price insensitivity makes patients want unnecessary services
  - ▶ medical arms race – hospitals overspend on technology
  - ▶ However, the regulator must choose the right level of technology which keeps costs low but quality high – requires a lot of information; thus, not surprising that CON have had little affect on costs

## Physician Payments

- ▶ Medicare uses usual, customary and reasonable (UCR) payment mechanism – based on median charges of other doctors in the area
  - ▶ Problem: no incentive to charge less, incentive to charge more to raise median
- ▶ Some states use relative value scales (RVS) – assigns weight to procedure based on time required and complexity

## Physician Payments

- ▶ Restructured in 1989 by Congress to Resource-based RVS – also takes into consideration practice expenses and liability insurance
  - ▶ Problem: input prices don't factor in; that is, if double # of physicians, prices should go down, but since time/effort is same, then prices stay same
- ▶ sustainable growth rate (SGR) system – CMS sets a target rate of growth in payments and adjusts the payment schedule over time with this

## Antitrust laws

Laws governing firm behavior to try to increase competition, aimed at monopolists or oligopolists

- ▶ Sherman Act (1890): prohibits “all contracts, combinations and conspiracies in restraint of trade”
- ▶ Clayton Act (1914)
  - ▶ prohibits **tying contracts**  
(have to buy 2nd good exclusively from seller)
  - ▶ prohibits **acquisition** by one corporation of another’s shares if these acts are likely to reduce competition or tend to create monopoly.
  - ▶ prohibits **directors** of one company from sitting on the board of a competitor’s company.
  - ▶ if could prove damage by an illegal arrangement, can recover 3 times the damages

# Antitrust Laws

- ▶ Federal Trade Commission Act (1914)
  - ▶ **established FTC** as an independent agency
  - ▶ authority to **prosecute unfair competition**
  - ▶ prevent false and misleading **advertising**
- ▶ Exceptions
  - ▶ firms that do not conduct interstate commerce; because Medicare is a big payer, this does not exempt hospitals
  - ▶ insurance companies are exempt because regulated by state law; but the exemption is narrow
  - ▶ lobbying activities are exempt

# Food and Drug Administration

How pharmaceuticals come to the market:

- ▶ basic investigator-initiated research at universities sponsored by NIH, not linked to application yet
- ▶ commercial application becomes apparent, get patent
- ▶ drug companies buy the patent, continue research on more applied level
  - ▶ spend 20% of sales revenues on research
  - ▶ 1000 compounds are evaluated for every 1 that enters clinical trials

## FDA drug testing

- ▶ Preclinical testing, R&D with **animal** testing  
*average 18 months*
- ▶ Phase I trials – initial **safety** testing on humans, 20-100 voluntary patients, 30% of drugs fail
- ▶ Phase II trials – initial **efficacy** testing, several hundred patients, 50% of drugs fail
- ▶ Phase III trials – extensive **efficacy and safety** testing  
*3 phases take an average of 5 years*
- ▶ **New Drug Application (NDA) Review**, 20% of all drugs brought to FDA receive marketing approval  
*average 24 months*
- ▶ Phase IV – postmarketing surveillance, doctors and pharmacists are required to submit any adverse events

## Other Regulations

- ▶ US law prohibits consumers from directly purchasing drugs – need prescription
- ▶ Patent law – protects firm's investment in R&D because chemical formula is known (required by FDA)
- ▶ licensure of physicians, dentists, psychologists, nurses, pharmacists, physical therapists, social workers, dental hygienists, soon public health workers
- ▶ quality certification of hospitals, medical schools, etc. (some voluntary, but if not, then state might mandate)