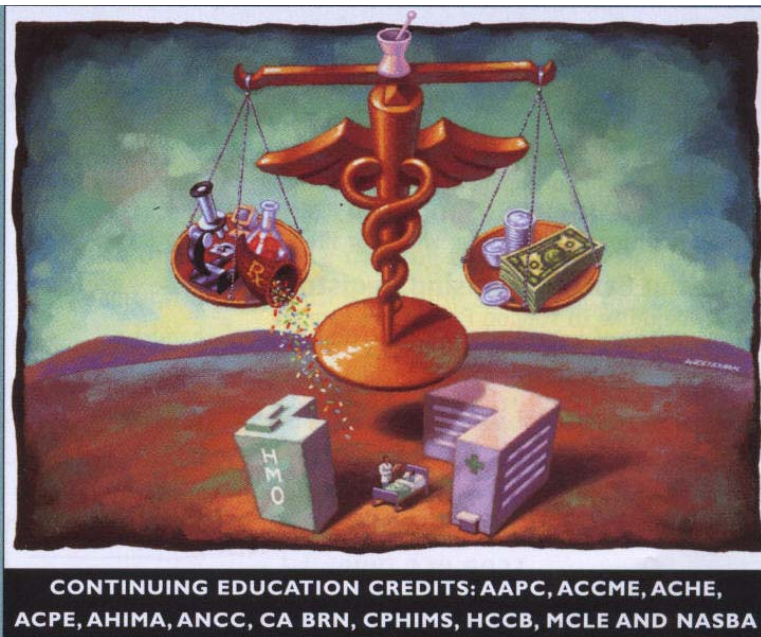


THE PHARMA, BIOTECH AND DEVICE COLLOQUIUM

ON THE CAMPUS OF PRINCETON UNIVERSITY • PRINCETON, NJ




Monday, June 7, 2004, 4:15 – 6:00 pm

**Law School for Pharmaceutical and Medical
Device Manufacturer Executives**

The Keys to the Kingdom

**Edwin D. Rauzi
Davis Wright Tremaine
Seattle, WA**

A stack of several books is shown, with the top book being light blue and the others in various colors like brown and red. The books are slightly out of focus. Overlaid on the top book is the text:

**Want a new job?
But not ready to
waste 3 years in
law school?**



Do you know that many states do not require a law school diploma to practice law?



ABRAHAM LINCOLN

The 16th U.S. President

1861-1865

**Why not
“Read the
Law,” like
Lincoln
did!**

OSI LB

**The analytical
concepts that
lawyers
(should) use in
analyzing legal
issues and
identifying
solutions**



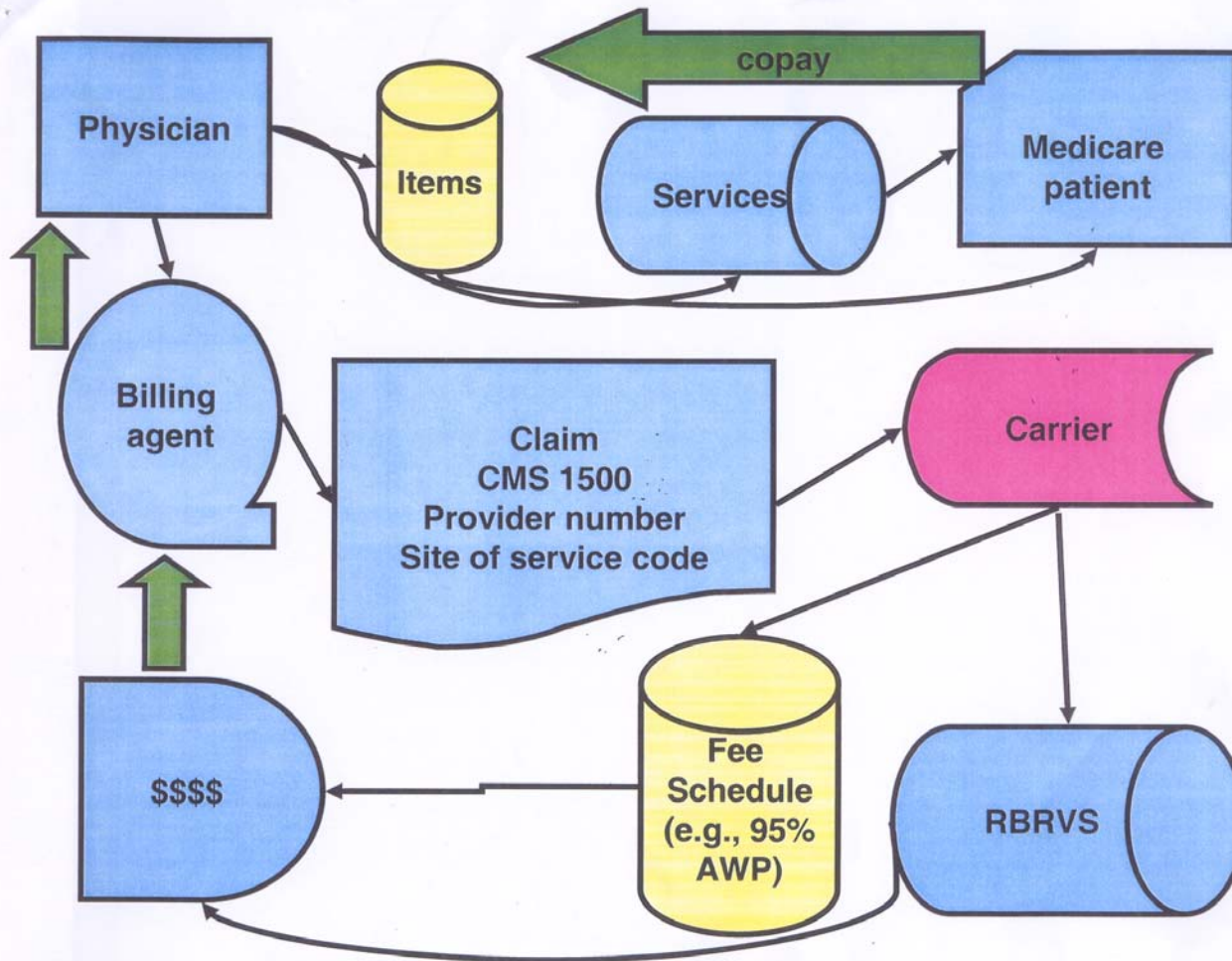
***Everything you
need is in this
book, But you
must act now!
Send \$19.95
Do it TODAY!~***

Chapter One: Each legal relationship involves no more (and no less) that two persons (or entities)--



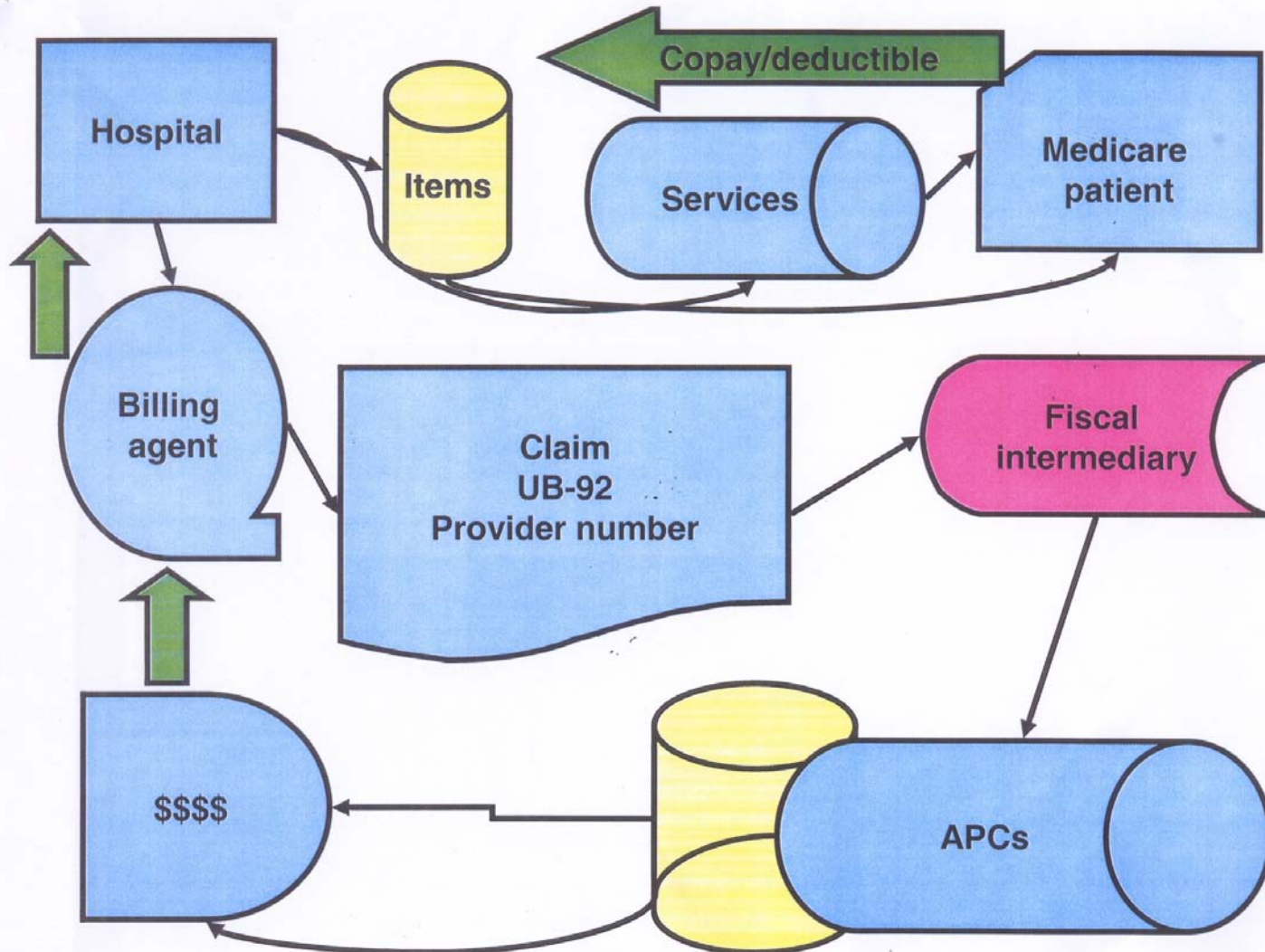
Just like basketball, it ultimately comes down to a game of “One on One.”

Chapter Two: One encounter can implicate many legal relationships--



.. and many rules

Chapter Three: A very similar encounter can implicate vastly different legal relationships (and rules)--



Chapter Four: Duty is behavior imposed upon an actor--

Can you tell who is supposed to act (or refrain from acting)? Compare and contrast

“Physician shall receive vast sums of money”

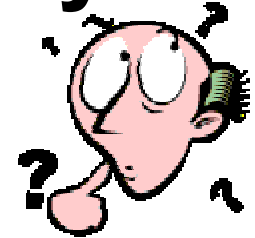
~with~

“Hospital shall pay Physician \$200 per hour, measured in increments of no less than a quarter hour (rounded up) for the duties of the Medical Director of the Department defined in Exhibit A.”

Chapter Five: There are three types of legal duties--

- Most duties are *prohibitions* (e.g., don't pay kickbacks)
- A few duties are *normative* (e.g., if you want the brand, you need to write "Dispense as Written" (*in green ink on Wednesday on an even calendar date*))
- Very few duties require a person to *act* (e.g., register for the draft, pay your taxes)

Chapter Five: One relationship may involve more than one legal duty--



If we satisfy the Anti-Kickback safe harbor, how can we possibly be at risk for a Stark violation?”

If we satisfy Stark, how can we possible be at risk for an Anti-kickback violation?”

If we satisfy the IRS that there is no private inurement or benefit in the deal, how can we possibly be at risk for Stark and Anti-Kickback violations?”

Chapter Seven: Sometimes, only Hohfeldian categories will do--

In 1913, Professor Wesley Hohfeld posited that there were only four fundamental legal concepts--

Legal Concept
RIGHT
PRIVILEGE
POWER
IMMUNITY

In any legal relationship, if a concept is “true,” then it has consequences for the other party– one concept can’t exist without the other

Legal Concept	Correlative
RIGHT	DUTY
PRIVILEGE	NO-RIGHT
POWER	LIABILITY
IMMUNITY	DISABILITY

If one concept is “true,” then other concepts cannot be true--

Legal Concept	Opposite
RIGHT	NO-RIGHT
PRIVILEGE	DUTY
POWER	DISABILITY
IMMUNITY	LIABILITY

Hohfeld Correlative Example #1

- **CONCEPT:** RIGHT
- **STATEMENT:** As a shareholder, I have a right to vote on directors.
- **ILLUSTRATION:** The board must hold elections each year. I have a RIGHT to demand that elections be held. The board has a correlative DUTY to hold them.

Hohfeld Correlative Example #2

- **CONCEPT: PRIVILEGE:**
- **STATEMENT:** Shareholders can write in Martha Stewart (if they want) as a director.
- **ILLUSTRATION:** A shareholder has a PRIVILEGE to vote for whomever he chooses. The board has a correlative NO-RIGHT to demand that the shareholder make good choices.

Hohfeld Corellative Example #3

- **CONCEPT: POWER**
- **STATEMENT:** Shareholders can vote to amend the bylaws.
- **ILLUSTRATION:** Shareholders have the **POWER** to amend the bylaws to change the timing of annual meetings. The board has a **LIABILITY** to follow shareholder-initiated bylaw changes.

Hohfeld Correlative Example #4

- ***CONCEPT:*** IMMUNITY
- ***STATEMENT:*** The board cannot manipulate the voting process.
- ***ILLUSTRATION:*** A shareholder has an IMMUNITY from the board fooling with the voting process. The board is DISABLED from requiring that votes be cast using only Bic pens.

Final Exam

- **Do American citizens have a “right” to health insurance?**
- **Do pharmaceutical manufacturers have a “privilege” to limit sales to Canadian pharmacies?**
- **Does Congress have the “power” to impose price controls?**



**No animals were
harmed in the
creation of this
presentation; and**

**No original
thoughts were
expressed**