Medicare Payment System Evolution:

What's In It for Medical Devices?

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As my fellow panelists have pointed out:

•Appropriate incentives for device use are a big deal in every payment system covering settings in which devices are used.

•Controversies exist both within individual systems, and across their boundaries.

•Most major "reforms" on the horizon are innocent of any explicit clue about how to improve incentives for optimal device use.

This state of affairs flows from generic problems:

•Medicare pays for "services of providers" – not "services" *per se.*

•Payment systems are calibrated to make cross-provider comparisons – not establish cross-service relativities.

•Over time, entropic tendency for provider proliferation.

•With each passing year, "cross-site neutrality" becomes more elusive.

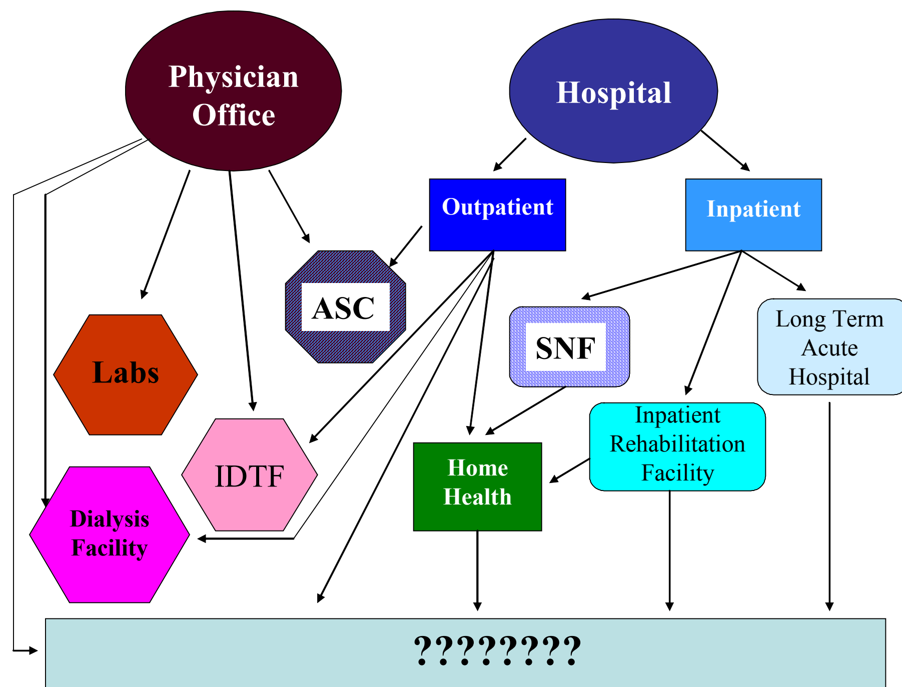
In the Medicare system:

- Device coverage is "incident to" whatever a provider does – not covered directly.
- Vague findings regarding "medical necessity" – rather than more device-specific criteria – now define coverage.
- No explicit consideration of how to pay for devices – and no channels of information to find out what they cost.
- In these systems, accurate reimbursement is often a matter of dumb luck.

The prospective payment systems:

- Are really fancy case mix indexing systems designed to support cross-facility payment comparisons.
- They are neither designed nor calibrated to produce accurate estimates of absolute (or even relative) cost of particular technologies.
- CMS defends against "micro-costing" on grounds it would foul up the accuracy of case mix measurement.
- This theology fails to apprehend the "micro-incentives" created by the failure to "micro-cost."

As time goes by, there's a tendency toward "entropic doom":



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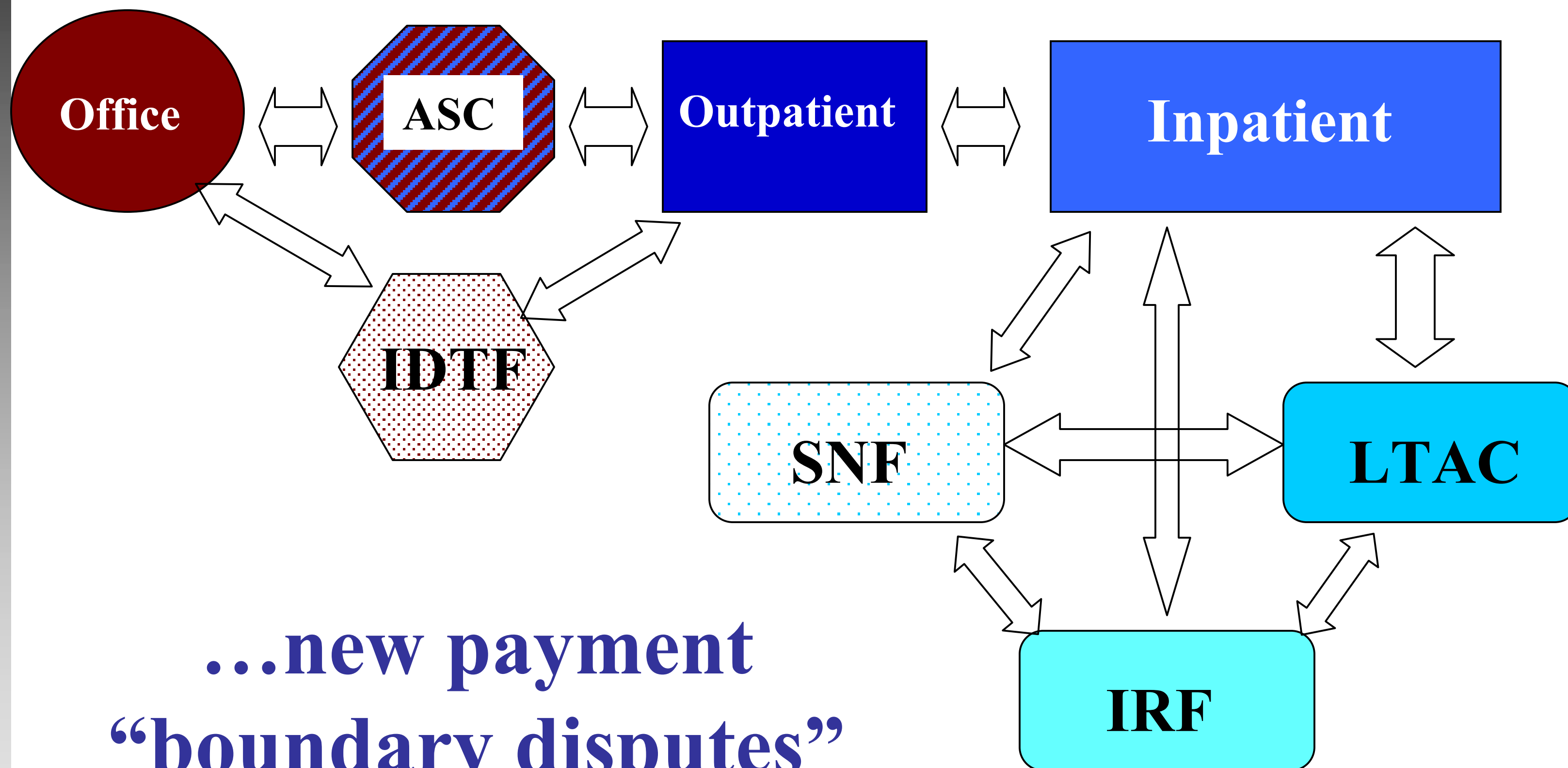
As each new provider type proliferates…

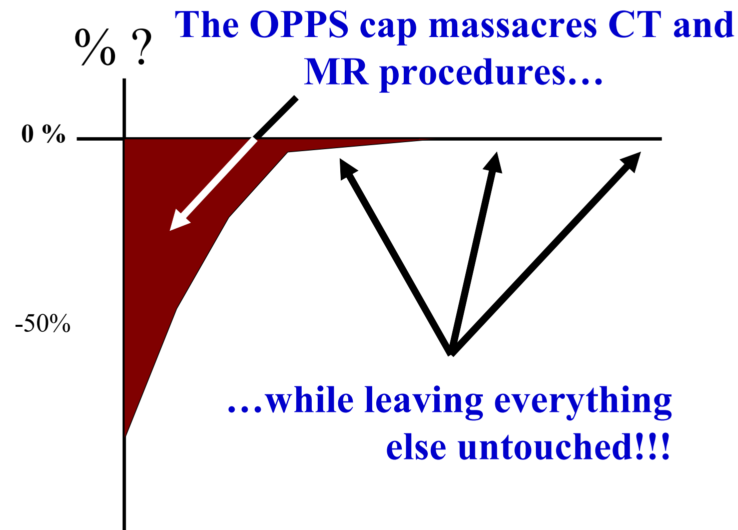


…new payment "boundary disputes" emerge!!

These disputes can't be made to go away!

- Disparities in granularity across payment systems in different setting makes cross-site calibration impossible.
- The inaccuracy of device-level cost comparisons even within payment systems make cross-system comparisons meaningless.
- Differences in scaling of conversion factors would confound comparisons even if relativities were perfect.

When policymakers try cross-setting "lesser of" policies…



…they get the kind of hash they just made of diagnostic imaging in the DRA!

What does all this have to do with devices?

- It tells us that, working within the walls of the present payment systems as they are currently evolving, obtaining accurate payment and neutral payment incentives is **physically impossible.**

- If we want a more rational payment system for medical devices, we going to have to start with a blank sheet of paper!

There's a hell of a fine Universe next door. Let's go!!!

e.e. cummings

This wouldn’t be a piece of cake for the industry:

- A “doubly neutral” payment system would require an explicit (probably evidence-based) coverage policy.
- It would require an explicit site-neutral payment for all uses that might limit payment differentials across comparable products for policy reasons.
- It would demand far greater price transparency than is now achievable under current industry practices.
- Prediction: we won’t go there until things get a hell of a lot worse than they are today.

So what do you do today?

•The days of "build it and they will buy" are over.

•Reimbursement implications need to be taken into account far earlier in the product development process.

•Everything we know about "price acceptance" in the Medicare and managed care marketplace will be obsolete in 3-5 years: plan for far more pervasive sticker shock.

•Expect pricing differentials to be henceforth justified only when clinical effects are materially different – not just new "features and benefits".

So what do you do today? (continued)

•For most multi-product companies, pipeline pruning is probably in order.

•Expect more emphasis on focusing R&D dollars on projects that suggest strong potential for clinical differentiation.

•Companies with only one or two products (as well as development stage companies) will find it hard to attract capital unless they clearly demonstrate that they “get it”.

So what do you do today? (continued)

- For current and imminent products, reimbursement "pull-through" is increasing in complexity geometrically.
- Risk associated with site-of-service payment differentials will become much more acute.
- In a budget neutral/budget negative environment, real victories in reimbursement will be rare.
- In this environment, convincing the end customers that you're working tirelessly on their behalf may be the only thing that can be accomplished!