Is Medicare Zero for Three? Diagnostics Policy Proposals for CY2014

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Each July, the Medicare agency makes policy proposals for changes in reimbursement for services delivered by physicians, hospital outpatient centers, and independent laboratories. For CY2014, CMS proposed three major policy changes impacting laboratory services. CMS proposed to revisit all prices on the Clinical Laboratory Fee Schedule, to determine whether technology changes over 5 to 30 years (depending on the code) should trigger administrative repricing, and by how much. CMS proposed to cap prices paid to independent labs for physician molecular pathology procedures – those priced in RVUs – based on a crosswalk to payment rates for hospital outpatient services. Finally, CMS proposed to bundle all diagnostic tests, including laboratory tests, to visits or procedures where the test was used or ordered by a physician. Each of the three proposals represents a major change in policy, and the implementation of each of them raises substantial problems .

SUMMARY

Each year, Medicare issues three bodies of regulations, policies, and fee schedule changes for the upcoming fiscal year – one each for the inpatient system, for the hospital outpatient system, and for the physician fee schedule system. After 60 days of public comment, and 60 days of internal decision-making, CMS sets its final policies for the next fiscal year, which begins about 60 days later.[1]

This year CMS proposed three major and independent changes in laboratory policy. Two were published in the Physician Fee Schedule proposed rule, and one in the Hospital Outpatient Payment System proposed rule; all were released for public comment on July 8, 2013.

CLFS Technologic Revaluation: CMS has statutory authority to revalue the prices of the clinical laboratory fee schedule (CLFS) based on changes in technology. However, CMS has never used this authority.

CMS proposed to review all clinical chemistry (CLFS) prices over the next five years, assessing "technologic change" by comparing technology in place at the time each code was priced with current technology, and re-pricing each test accordingly. CMS does not state how it will determine either 1980s or contemporary technology (technologies), calculate the difference between them in costs, and extrapolate from the difference to the administratively accurate size of a revision in the CMS CLFS price.

Cap Pathology Tests at OPPS prices: CMS sets physician fee schedule prices based on practice expenses, physician time and other labor, and indirect costs for each service. In contrast, CMS sets hospital outpatient prices in ~350 groups called Ambulatory Payment Categories (APCs), each of which includes between 1 and 200 different services (CPT codes).[2] A single final price is set each APC, determined by using reported hospital charges reduced by departmental "cost to charge ratios" multiplied by a relative value factor. For example, if a hospital department performs only $100 tests, and that department has $1M of expenses and $3M of charges, its laboratory department cost-to-charge ratio is .33. In an extremely simplified model with only one test in an APC, and considering no other CMS pricing factors, the APC would be assigned a price of $33. More realistically, the hospital would be a medley of very different tests at different prices all collated by CMS into that APC, with an unpredictable APC price.

CMS proposes that Physician Fee Schedule RVU price for a pathology test CPT code is higher than the APC price for the group of tests it is aggregated to, CMS will override the RVU pricing system and use the lower APC price. For some pathology tests, this will cut CY2014 CMS pricing by 50-70% or more. Remarkably, CMS never discusses the obvious problem that the price determined for an APC simply falls between higher and lower cost tests that are crosswalked to one APC. For example, services with real costs of $100, $200, $300, might be placed in one APC with a final price of $150. The APC payment of

$150 for any of the services is only half the value of the most costly service, and is 50% more than the value of the least costly service. Therefore, the APC price may be lower than the CPT RVU price when all calculations are correct.

Bundle Diagnostic Tests to Outpatient Visits and Procedures. In the hospital outpatient proposal, CMS describes laboratory tests, imaging, and several other categories of supplies or services as "ancillary to" another event – such as a physician visit or urgent care procedure. While I found this proposal the most difficult to understand, it appears that a $1000 PET scan might be "bundled" inside the payment for a $100 office visit.

Many policy experts currently favor larger episodes of care as the unit of reimbursement, but bundling medically necessary $1000 procedures inside unrelated $50 to $100 procedures seems to create enormous "perverse incentives" to perform the costly procedure at an arbitrarily different site, on a different day, or at a different institution. This would predictably lead to witch-hunt audits to determine if the day and location when the second service was provided had been displaced in a way that was "medically necessary" or displaced to avoid the bundling rule. This concern doesn't occur in other types of bundling, such as when a nuclear medicine tracer is bundled to an imaging scan, or when bandages and intraoperative nursing care are bundled to an outpatient surgery.

Summary: Taken as a group, the three policy proposals show remarkable ingenuity and reflect a deep seated agency desire for policymakers to pull their weight in finding creative ways to reduce costs and prices in the U.S. healthcare system. While granting an "A for effort," or "I for ingenuity," all of the three proposals portend major implementation problems and none should be finalized as proposed.

It's not a problem unless you have a solution.

Jason Reitman, Screenwriter/Director, Up in the Air (2009)[3]

- **Diagnostic Tests Provoke Policymakers**
- **Diagnostic Tests Are Transforming Healthcare**
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Diagnostic Tests Provoke Policymakers

Concern in the government about American health care costs dates to the Truman and Eisenhower administrations if not before.[4] General concerns about medical costs are much older: over a century ago, Freud described the anxiety provoked by a dream where he was accosted for hospital costs he could not pay.[5]

As part of the cost concerns, health policy experts have bemoaned the overutilization and costs of laboratory tests since the early 1900s. In 1912, a Parisian physician touring the US reported that laboratory tests "like rain, descended from heaven on the just and the unjust," and in 1940s, Harrison, of Harrison's Internal Medicine, decried a "modern" tendency for 5 minutes interviews to be followed by five days of diagnostic tests.[6] Viewed in this line, CMS's three new policies on laboratory test reimbursement reflect a longstanding policy interest in controlling the utilization of diagnostic tests.

I believe that laboratory tests suffer four stigmas that contribute to the frequency of "incoming fire" from policymakers. **First, lab tests are perceived as <u>easily ordered</u>.** Whereas a history and physician must be performed by a physician over time, and a surgery undertaken under elaborate conditions, and a drug must be procured and taken by the patient under some risk, laboratory tests can be easily checkmarked by the physician on an order form. **Second, lab tests are viewed as <u>abstract</u>.** Hospitals perform surgeries, such as transplants, of phenomenal complexity that even layman can grasp. Drugs are widely known to emerge from elaborate clinical trials, and are manufactured under complex conditions that the patient can only guess at when he sees a pill in his hand. Laboratory tests are in the realm of the imagination and abstract – you hear on the phone that your cholesterol is 150, which is fine, or a physician sees your cholesterol value as the digits 1,5,0 on a screen or a slip of paper. The laboratory digits roll by endlessly, like numbers in a phone book, patient to patient, from month to month. **Third, laboratory tests are <u>getting more expensive</u>** because they now bring to patient care

complex molecular technology that was science fiction twenty or thirty years ago, and the craft of PhD researchers only ten to fifteen years ago. New molecular tests frequently require unprecedented amounts of research for their validation. **Fourth, people have no anchor for the "correct" cost of molecular tests**, and often hear very confusing anchors.[7] For example, one might hear the cost of sequencing the human genome has dropped from some fanciful figure – say, $50 million dollars – to a few thousand dollars. This conflates the cost of obtaining raw genetic information – bits and bytes – with the resources required to produce clinically validated and medically useable data. The apples and oranges comparison is lost on the listener.[8]

Diagnostic Tests Are Transforming Healthcare

The price of everything and the value of nothing…?

While the policy proposals reviewed in this white paper may seem draconian and depressing, we should remember the larger context. The value and clinical impact of molecular tests is very high, will never go away, and will become higher. Molecular medicine is widely viewed as a transformational change of our times, such that we will look back in twenty or thirty years and realize that a fundamental revolution in healthcare has taken place.[9] The goal of the human genome project has been to understand disease and improve healthcare.[10] This genomic revolution is playing out at two levels:

- Broadly, our knowledge of the varieties and mechanisms of disease at a cellular and genetic level is advancing rapidly. This knowledge creates know-how that can be brought to biomedical research and pharmaceutical science.
- Even more rapidly than pharmaceuticals can be created, genes and gene expression can be the target of diagnosis. The same laboratory tools that map the genome in research are rapidly playing a significant role in healthcare services.

As they have been throughout history, diagnosis and diagnostic methods are fundamental to the practice of medicine. The difference is that we can now rapidly and with precision determine the abnormalities that drive disease process and cause cells to go out of control, as in cancer. Whereas for a historical lab test, for cholesterol or glucose, need only measure one number (your level of chemical "X"), genes can be spliced, expressed, vary among the population, and be mutated in literally hundreds or thousands of ways in disease. No two cancers are alike. And the differences between each cancer and others in a hundred patients with breast cancer, prostate cancer, or colon cancer may be vitally useful. We will need a regulatory science that can cope with the spectacular variety exhibited by human disease through molecular tests. And we will need a reimbursement system that can rapidly evaluate tests and promote their use in delivering better, more effective, and more efficient healthcare.

Primer to the Policy Analyses:

How CMS Payments are Usually Tied to Production Costs

The Medicare agency pays for virtually all supplies and services based on their cost to the final provider who provides them for the patient.

For example, hospital inpatient and outpatient costs are based on "charges reduced to cost," then aggregated into buckets, distilled into relative values, and finally priced. As a result, inpatient and outpatient Medicare payments are based on calculations that are usually at or somewhat below the hospital's average cost. For inpatients, the policy system is called the Inpatient Diagnosis Related Group/DRG system (dating to the early 1980s). For outpatients, the policy system is called the Ambulatory Payment Category/APC system, dating to the early 2000s).

Turning to the physician fee schedule, the Medicare price for each CPT code is based on meticulous estimates of physician time, other direct labor such as nurse or technician time for a particular service, disposable supplies, capital equipment, and indirect costs. There are other Medicare payment systems, such as those for home health and hospice care, in which prices are calculated differently, but those are regularly audited by one or another body for profit, and may be reduced by policy or legislation if provider profit exceeds a few percent.[11]

Given this agency paradigm to pay for diverse healthcare services at their costs, the three policy proposals discussed in this white paper are part and parcel of CMS' agency-wide costing efforts.

One more aspect of Medicare must be discussed before presenting the three CY2014 policies. Under Medicare law, laboratory medicine tests are divided into two quite different policy categories.

- **Physician laboratory tests.** Those laboratory tests with a substantial and required physician interpretation component fall on the RVU-based Physician Fee Schedule system just discussed. The 2nd Policy Proposal, Cap Pathology Tests by APC Rates, addresses this test category. Prices under the RVU Physician Fee Schedule current system are set by surveys that catalog technical inputs such as technician time, capital equipment usage, and supplies and disposables costs, along with minutes of physician time.
- **All other laboratory tests** fall in the domain of clinical chemistry and related laboratory sciences (including most molecular genetic tests) are paid on the Clinical Laboratory Fee Schedule. The 1st Policy Proposal, CLFS Technologic Revaluation, address this category of test prices. Prices on the CLFS were paid based on year to year local estimates of prevailing charges until 1984, when prices were locked down except for irregular annual updates for inflation, or schedule-wide decrements for fiscal policy reasons. The current CLFS looks like this, but in total contains 72,000 cells (about 1200 rows x 60 columns):

	MS	AR	LA	IN	AK	OR	WA	WI	IL
	00512	00520	00528	00630	00831	00835	00836	00951	00952
HCPCS	Loc 00	Loc 00	Loc 00	Loc 00	Loc 00	Loc 00	Loc 00	Loc 00	Loc 00
81000	$4.48	$4.48	$4.48	$4.48	$4.48	$4.48	$4.48	$4.48	$4.48
81001	$4.48	$4.48	$4.48	$4.48	$4.48	$4.48	$4.48	$4.48	$4.48
81002	$3.62	$3.62	$3.62	$3.62	$3.62	$3.62	$3.62	$3.62	$3.62
81003	$3.18	$3.18	$3.18	$3.18	$3.18	$3.18	$3.18	$3.18	$3.18
81003	$3.18	$3.18	$3.18	$3.18	$3.18	$3.18	$3.18	$3.18	$3.18
81005	$3.07	$3.07	$3.07	$3.07	$3.07	$3.07	$3.07	$3.07	$3.07
81007	$3.63	$3.63	$3.63	$3.63	$3.63	$3.63	$3.63	$3.63	$3.63
81007	$3.63	$3.63	$3.63	$3.63	$3.63	$3.63	$3.63	$3.63	$3.63
81015	$4.31	$4.31	$4.31	$4.31	$4.31	$4.31	$4.31	$4.31	$4.31
81020	$5.22	$5.22	$5.22	$5.22	$5.22	$5.22	$5.22	$5.22	$4.03
81025	$8.96	$8.96	$8.96	$8.96	$8.96	$8.96	$5.33	$8.96	$8.96
81050	$4.25	$4.25	$4.25	$4.25	$4.25	$4.25	$4.25	$4.25	$4.25
82000	$17.55	$8.17	$17.55	$17.55	$17.55	$17.55	$17.55	$13.19	$14.08
82003	$21.40	$28.66	$28.66	$28.66	$28.66	$28.66	$25.57	$28.66	$28.14
82009	$6.40	$6.40	$6.40	$6.40	$6.40	$6.40	$6.40	$6.40	$6.40
82010	$11.57	$9.93	$11.57	$11.57	$11.57	$11.57	$11.57	$11.57	$11.57
82010	$11.57	$9.93	$11.57	$11.57	$11.57	$11.57	$11.57	$11.57	$11.57
82013	$15.82	$15.82	$15.82	$15.82	$15.82	$15.82	$15.82	$15.82	$15.82
82016	$19.63	$18.92	$19.63	$19.63	$19.63	$19.63	$19.63	$19.63	$19.63
82017	$23.89	$23.89	$23.89	$20.65	$23.89	$23.89	$7.78	$20.41	$23.89

Figure One:
Clinical Laboratory Fee Schedule (CMS, 2012)

Net-net, the CLFS now pays about $8 for a test that would have been $10 in 1984 and inflated to $22 due to intervening inflation.[12]

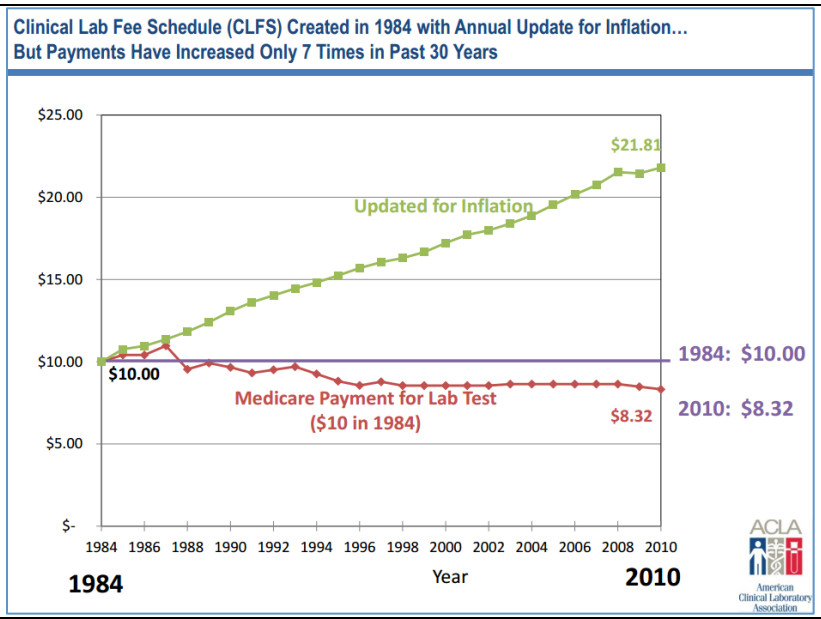


Figure Two:
http://www.acla.com/sites/default/files/May%202013%20ACLA%20Hill%20Leave%20Behind.pdf

POLICY ONE:
CLFS Technologic Revaluation

Background

As was shown in Figure Two, most prices on the Clinical Laboratory Fee Schedule (CLFS) were set in 1984 and in real dollars, they have eroded over time due to inflation. As noted by the American Clinical Laboratory Association in its comment to CMS on this proposed rule, the erosion in real price should not be viewed in dollars alone. Over the same years, laboratory regulations at both the federal and state levels have become vastly more complex, through the passage of CLIA 1988 and other laws and regulations. Indirect costs such as health care and malpractice have risen substantially, as well as administrative costs such as working with RAC contractors, against whom clinical laboratories have unique challenges as they do not possess the great body of medical records and paperwork that justifies any particular test ordered. Overall, competition in the laboratory industry has led to substantial consolidation over the past two to three decades, and even the largest national laboratory providers have profits not higher than the 5-10% range.[13] The several industry segments – large labs, regional labs, hospital internal and outreach labs, and specialty labs – all compete actively against one another. Lab trade journals are now replete with stories about narrow profit margins and the struggle to reduce labor or equipment costs still further to survive within today's payment systems.[14] So far this year, CMS has repriced molecular genetic tests (which switched from one coding system to another) in some cases substantially, by 50% or more.[15] Meanwhile, commercial insurer Aetna has tied some lab payments to 50% of the prevailing Medicare fee schedules – though in part to deter business from labs not favored in its in-network, out-of-network contracting process.[16] In June 2013, the OIG noted that Medicare prices, although dropping in real dollars as we have seen, may be higher than prices of Medicaid plans, but this unavoidable, since by law Medicaid lab test prices can only be the same, or lower, than Medicare prices.[17]

The CMS CLFS Proposal[18]

The primary thrust of CMS's discussion is to note its discomfort with the "fixed" CLFS schedule, the rarity of "fixed" schedules among its payment policies, and the multiple sources which document technological change in the modern laboratory industry. For justification of its positions, federal authorities are favored. Thus:

- ✓ A 2000 Institute of Medicine report described "rapid and dramatic innovation" in lab technology, with advanced equipment and information technology "[having] all made testing more efficient and automated."[19]

- ✓ Points of care tests are now "smaller, cheaper, and more automated." (Inference that POC tests performed and billed in physician settings are overpaid on the CLFS.)

- ✓ At a larger scale, genome sequencing costs have dropped "dramatically" from $95M/genome in 2001 to $5,700/genome in 2013 (citation to: genome.gov).

- ✓ Medicare data shows that those tests which have transitioned from stack codes to CPT-specific codes "show that the costs of performing these tests have decreased."[20]

- ✓ CMS adds that "in general, technology is most expensive early in its life cycle" and payments should decrease due to "the general downward trend of costs once technology has had the opportunity to diffuse."

In summary, given this fact pattern, CMS concludes it should and will "establish a process to reconsider payment amounts."[21] CMS finds a clear authority on which to create such a new process, because SSA 1833(h)(2)(A)(i) authorizes the Secretary the authority to adjust CLFS prices "annually" using [quote]:

> "***such other adjustments as the Secretary determines are justified by technological changes***."

CMS then proposes to adjust groups of CLFS codes annually, beginning with the oldest codes, until all CLFS tests have been reviewed.

Because the new policy apparatus hinges on a definition of "**technological changes**," CMS provides us with one both in the preamble and in the proposed regulatory revision at 414.511:

> **414.511 (Proposed):**
>
> **(a)** CMS may make adjustments to the [CLFS] as CMS determines are justified by technological changes. [Repeating statute]
>
> **(b)** Technological changes are *changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used.*

The above box displays the entire regulatory change; all other aspects of the new program would be "policy" implementing this brief regulation. Said differently, the sole regulatory change is to add a 20-word italicized definition of laboratory "technological change" to the Agency's current regulations.

Thus, the reader's credibility is stretched when CMS states that it has "codified the process" at 414.511. CMS has done nothing but provide a definition at 414.511.

CMS sketches what it will do if the proposal is finalized as proposed:

- Since the above rule will become active in CY2014 (1/1/2014), it will be first usable in the summer of 2014 to make changes for CY2015.
- Beginning in July 2014, in each summer's proposed rule, CMS would announce the codes it had chosen and reviewed, why there were technological changes, and what the new proposed price will be -- subject to 60 days' public comment.
- The rule aims to promote payment accuracy; toward this end prices may rise or fall.
- CMS proposes to begin its review with the "oldest codes" on the CLFS (unclear if this would be *all* the original codes on the 1984 CLFS, each being the same age on the CLFS, or codes chosen by age by looking to the 1970s volumes of the AMA CPT itself). The review of the 1250 CLFS codes will take "at least" five years. On an ongoing basis, codes less than 5 years old will not generally be reviewed, and codes reviewed will not be subject to re-review within 5 years. CMS seeks comment on how to prioritize codes for review; codes nominated for review by the public will be one consideration.

CMS seeks three types of comments. CMS seeks comments on (A) the proposed policy and (B) on alternatives for laboratory repricing. CMS closes this section by asking the public for comments (C) "*on technology change in…the health care sector in general*."

For this proposed rule, CMS and Stakeholders should consider:

- **Definition of Technology Change: What is missing?**
    - CMS has defined "technology change" as a change in many aspects of a laboratory technology, from supplies to equipment to staff. However:
    - CMS makes no acknowledgement that, <u>like drugs</u>, some particular advanced LDTs are developed with large research trials by one manufacturer/provider, therefore, the invested costs are vastly higher than the marginal costs of delivering one more test.
        - Since some LDTs require very large clinical trials and investments, like drugs, bringing them into existence must incorporate very high technological risk and a weighted expectation of profit over all similar up front investments, not only profit on successful products.[22]
        - New LDTs like next-gen sequencing require very elaborate costs in software and very sophisticated personnel. $1 in technologic costs in a hematocrit or glucose test probably has very limited overhead, but each $1 in technologic costs in very sophisticated and new tests will have high overhead costs.

- CMS policy staff make no comment at all that Medicare (in LCDs and NCDs) and its fellow HHS agencies AHRQ, PCORI, and CDC/EGAPP often find that laboratory tests lack enough data, and push the evidence bar for data are higher and higher.[23] Marginal costs support no R&D; prices must include considerations for R&D.

- Aside from problems raised by the critical need for research and investment costs, CMS provides no information on how it would crosswalk from technology costs to total costs. For inpatient and outpatient hospitals, and for the physician fee schedule, the calculation of total costs requires ***extremely complex accounting systems for indirect costs*** and these are settings that need not consider R&D and capital at risk in scientific ventures. Even if CMS identifies, e.g., a change in kit price, it has offered the public ***no mechanism at all*** to project this single technology cost into an appropriate comprehensive fee schedule price. For example, it would be impossible to price a pacemaker or new drug based on the cost of a battery or a chemical supply, and the problem is only marginally easier for lab tests.[24]

    - CMS makes no allowance that both IVD kits and LDTs require substantial validation and overhead in the performing CLIA laboratory, hence, change in kit prices (or supply prices) may be relatively small relative to total costs.

    - At large publicly held laboratories such as Labcorp and Quest, direct costs or costs of good sold are about 50% of revenue, suggesting that **kit costs** are likely no more than **25% of revenue**.

        - Most other costs for operations and SG&A would be the same if a particular kit cost dropped in price, therefore, a **20% drop in kit price** would cause only a **5% drop in total price.**

- The proposed process is precarious.

    - If inaccurate and unexpected data is suddenly announced by CMS on July 1, it may be very difficult to undertake the necessary surveys and wide-ranging data rapidly enough to comment within 60 days.

    - In contrast, CMS requests the RUC to reprice certain codes taking surveys over a one to two year time horizon. In other cases, CMS announces it one year's rulemaking it is reviewing a code in the next year, providing a one-year "head start" for stakeholders.

Conclusion:

- CMS must produce a more granular and explicit statement of the process it will go through to suggest (to extrapolate) new prices for comment from its proposed "technology review." Otherwise, stakeholders may be subject to an arbitrary and inaccurate process in July 2014, with no time to provide appropriate data and corrections.

- CMS has not demonstrated with confidence or example that the proposed process can be done at all.

POLICY TWO:
Cap PFS Tests at APC Rates

Laboratory tests fall on the Physician Fee Schedule when they require a substantial component of personal physician work for each test, such as occurs in the review of microscope slides. (These represent only about 50 of the 1300+ lab CPT codes.) For the purpose of Medicare payments, physician work was originally priced (in the 1960s and 1970s) by "prevailing charges," but the payment system was converted to tables of "relative value units" some twenty years ago. For example, a 30 minute office visit and a somewhat more intensive 20 minute procedure might be priced to the same "relative value" of physician work, before the consideration of other costs. In 1994, lawmaking required practice expenses to be resource based as well (initially for 1998, but delayed). In CY2007 rulemaking, CMS proposed to revise its practice expense system to a "bottom up" method, with the creation of numbingly elaborate supply and input tables for literally thousands of CPT codes. Physician time, the use of non-physician clinical labor, supplies, capital equipment, and the value of "indirect costs" for office overhead are calculated from surveys and other sources. Technology input costs, represented in real dollars in these tables, are discounted by about 50% before final CMS prices are calculated using an RVU conversion factor that turns Relative Value Units (such as 1.5) into prices (such as $51).

Every year, CMS discusses its concerns about inaccurate prices, for one reason or another. Media such as the New York Times, Washington Post, Wall Street Journal, and Washington Monthly have also published articles that question the validity of RVU based pricing.[25] [26] [27] [28] Just a few years ago, CMS proposed using federal procurement tables in lieu of its existing approach that primarily accepts professional input on market prices. CMS has lowered prices for advanced imaging by changing its accounting rules so as to lower the capital cost attributed to each CT or MRI scan. Last year, CMS complained that IMRT radiation therapy was on its books for a certain duration of time per patient, but CMS staff discovered marketing materials stating the per-session time was only half as long. CMS thus indicated that it took a dim view of various times and costs reported in the AMA RVU process.

This year, CMS notes that hospital outpatient (OPPS) prices, in its 250 Ambulatory payment Classification price levels, are nearly always significantly higher than the prices for services in physician offices. The AHA emphasizes that hospital outpatient costs are naturally higher than physician costs, and therefore a substantial price delta that favors hospital-based prices is fair.[29]

The "**OPPS RVU CAP**" proposal is introduced by CMS stating that in the future it will begin "using OPPS and ASC rates in developing PE RVUs." CMS notes that the payment in OPPS and ASC settings "typically exceeds the Medicare payment made for the same service when furnished in the physician office," due to the "higher overhead" for 24/7 readiness that hospitals must maintain.

But sometimes physician office prices for a CPT code are higher than Medicare would pay a hospital. CMS writes (p. 78:43296):

> [We] have found that for some services, the total Medicare payment when the service is furnished in the physician office setting exceeds the total Medicare payment when the service is furnished in an OPD or an ASC.
>
> When this occurs, we believe it is not the result of appropriate payment differentials between the services furnished in different settings.
>
> Rather, we believe it is due to anomalies in the data we use under the PFS and in the application of our resource-based PE methodology to the particular services.

CMS attributes these anomalies to the submission of information "by individuals furnishing the service," against whom CMS has "little means to validate whether the information is accurate or reflects typical resource costs." In other cases, CMS's cost data may be outdated for technologies where a "high growth in volume of a service" leads to a "decrease in the cost of expensive items." In contrast, CMS knows that its "OPPS payment rates are based on auditable hospital data and are updated annually." Therefore, CMS believes that:

> The non-facility PFS [RVU] payments rates for procedures that exceed those for the same procedure in a facility result from inadequate or inaccurate direct PE inputs, especially price or time assumptions, as compared to the more accurate OPPS data….[30]
>
> On these bases, we are proposing a change in the [RVU] PE methodology beginning in CY2014.

CMS states it will compare "the PFS payment rate for a service furnished in an office setting to the total Medicare payment to practitioners and facilities for the same service when furnished in a hospital outpatient setting." If the PFS payment is higher, then, CMS will limit the "nonfacility PE RVUs for individual codes so that the total nonfacility PFS payment amount would not exceed the total combined amount Medicare would pay for the same code in the facility setting." Since the physician

work payment in both locations is generally the same and thus cancels out (at least for pathology tests), in practical terms, this means lowering the RVU technical component for pathology tests to to match the APC rate.

This proposal involves no change in regulation. Rather, CMS lays out the policy rules it promises to follow. The rule will be applied only when at least 5% of the service is performed in the hospital outpatient setting. (For example, a test is performed nationally 1000 times, at least 50 of which are in the hospital outpatient setting rather than the free standing lab or office setting). The rule will not apply to imaging tests, because this are already capped at APC rates by legislation in 2007.[31] At least in the current, the CY2014 PFS RVU rates will be capped at the rates set for the corresponding APCs in CY2013 (e.g., now). This year-to-year matching is of interest because APC rates can vary markedly from year to year, whereas PFS RVU rates only exceptionally change more than a few percent from one year to the next.

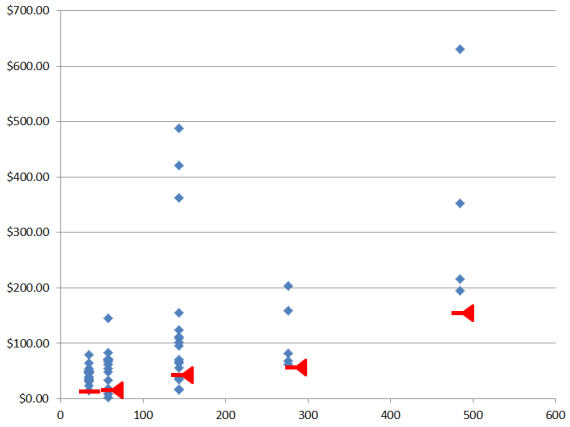
The College of American Pathologists, on July 19, 2013, posted the following table of the cuts to several key pathology services:[32] [33]

Top Ten Reductions to Pathology Services Based on Volume and Proposed Change					
88307	Global	Tissue exam by pathologist	-50%		
88342	Global	Immunohistochemistry	-27%		
88312	Global	Special stains group 1	-46%		
88313	Global	Special stains group 2	-45%		
88112	Global	Cytopath cell enhance tech	-22%		
88185	Global	Flowcytometry/tc add-on	-75%		
88309	Global	Tissue exam by pathologist	-30%		
88173	Global	Cytopath eval fna report	-25%		
88367	Global	Insitu hybridization auto	-60%		
88108	Global	Cytopath concentrate tech	-39%		

For this proposed rule, CMS and Stakeholders should consider:

- It's hardly surprising that some APC prices will be higher than some RVU prices, even when both systems work perfectly.
    - APCs are aggregates of services. This has two aspects. A small service may be in the same code as a larger service and the payment for that APC represents a "bundled" payment. (E.g. a $500 MRI scan uses a $100 contrast agent half the time, and the APC code pays $550 regardless.) But the APC also aggregates many different services, each of which trigger the APC payment. The number of major CPT codes aggregated into an APC range from 1 to over 200. APC 412, Level III Radiotherapy, has primarily one code, IMRT radiotherapy (77418). In contrast, APC 256, Level VI ENT Surgery, has some 225 codes in it.

- Imagine an APC has three services, with costs of $100, $200, and $300. They are place one APC, and because the cheaper services are more frequent, the average price set for the APC is $150. This means it overpays the cheaper service by 50%, and underpays the expensive service by 50%. It doesn't mean there is anything wrong with the $300 cost or price of the more expensive service.
- Below, I show the spread of CPT RVU prices for CPT codes classified in Outpatient APC groups 1-5 (CY2013 RVU prices and CY2013 APC prices):



- Clearly, there is little relationship between APC classifications 1-5 (the left to the right columns) and the RVU price of the several dozen CPT codes.
- The charge and cost-to-charge data from which CMS calculates APCs is extremely noisy. For APCs 342, 343, and 661 (Pathology 1, 3, and 5), 'costs' for tests by hospitals in each APC ranged from $1-$3095, $4 to $7685, and $10 to $24,986. For a single CPT code, cost (which may include multiples) submitted hospital costs (calculated from charges) ranged from $6 to $2708 for immunohistochemistry, 88342. On a CPT code line item basis, in this summer's OPPS amended data, Pathology II (APC 433) contains codes with median charges ranging from $40 to $349, almost a factor of 10, in an APC that would be priced at calculated APC median of $57 next year. It is no wonder that the costs or prices of some CPT codes are cut off when an APC rate is used as a cap.

- While CMS notes that hospital cost/charge data is "audited," it is globally audited: a hospital that has a $300M budget and submitted $1B in charges has a cost to charge ratio of .33. It does not mean the millions of CPT claims are audited, or that the setting of "prices" within a department such as laboratory medicine are necessarily based on cost. There is no reason they need be.
- It is unclear that CMS has the authority to do what it has proposed. The CLFS Technology Repricing has a clear statutory authority (in this white paper, Proposal 1), as does the Test Bundling Proposal (in this white paper, Proposal 3), and in both cases CMS clearly lays out its statutory authority during rulemaking. For this proposal (under discussion) it is entirely unclear that CMS has statutory authority, because the statute places CMS is under explicit and statutory guidance to use practice expenses alone to set RVUs (SSA 1848(c)(2)(C)(ii)). As a policy expert, I

can note that CMS has a long history of altering PFS CPT RVU values - only - by adjusting actual bottom up costs and valuations, for supplies, physician time, etc, or for capital equipment norms. That is, CMS has always hewn closely to the actual wording of the statutory instruction.

POLICY THREE:
Bundle Outpatient Diagnostics to Other Services

In some ways this is the simplest, and in others the most complicated CMS policy proposal. The hospital outpatient payment system is based on packaging services; there are only several hundred Ambulatory Payment Categories into which many thousand CPT codes are aggregated. Some APCs contain only one major services; others contain over 200 CPT codes. (See prior section on Policy Two.)

CMS proposes to move seven types of services from line item payment to bundled or packaged payment.[34] These seven services are: (1) Drugs used as a supply for a diagnostic test; (2) Drugs used as supplies during surgical procedures, (3) clinical diagnostic laboratory tests, (4) procedures described by add-on codes, (5) Ancillary services (including pathology tests), (6) bypass list diagnostic tests, and (7) device removal procedures. CMS provides a separate rationale for each policy change.

A. OUTPATIENT BUNDLING: FOR CLFS TESTS

For CLFS tests, CMS flags its broad authority to designate APC category and bundling policy under SSA 1833(t)(1) (Rule, p. 43572-3). In its original CY2000 rulemaking, CMS excluded from APC bundling those services that were payable as hospital outpatient patient services under an existing fee schedule, which is why the CLFS tests have never been inside of APCs. (See 65 FR 18442; 42 CFR 419.22).

However, just as our current Constitution reflects a revision to make a "more perfect Union" that the prior one, CMS intends to make the OPPS "a more complete Prospective Payment System" by means of "packaging the payment of items and services when they are provided along with the primary services they support."

CLFS laboratory tests fall under the concept of services that are "integral, ancillary, supportive, dependent, or adjunctive to a primary service." CLFS tests will be bundled when they are <u>provided on the same date of service</u> as a primary service and ordered by the same practitioner who ordered the primary service. The current rule for hospital outpatient tests is that they must be billed by the hospital when they are drawn at the hospital (e.g. blood draw or tissue specimen), but they are paid separately on the CLFS. The new rule appears to apply if the specimen is drawn at the hospital or elsewhere on the same day as the "primary service." To my reading, the new rule would not apply if the specimen is

drawn at the hospital or elsewhere on the next day, because the blood draw sets the date of service for laboratory tests, and the date of service would no longer be the same as the date of the primary service, so the test would no longer be "provided on the same date of service."

CLFS tests will not be bundled when they are the only service provided on the data of service, or, when ordered "for a different purpose than the primary service by a different practitioner." (That is, if Dr. A sees the patient for anemia, while Dr. B next door orders the hematocrit, although Dr. B is a different practitioner the service is still for the primary service.) Two categories of laboratory tests will fall outside the new packaging rule. These are first, genetic/genomic tests are excluded from the packaging policy, for the time being.[35] Second, laboratory tests that fall outside the new packaging rule will still be paid on the CLFS on a 14X bill type [typically, laboratory services for non patients].

CMS considered but rejected a dollar-cutoff for this packaging policy. A dollar cutoff is used for packaging drugs (e.g. if the hospital is giving chemotherapy, $20 drugs are packaged but $1000 drugs are not.) But, CMS notes that in general, it packages *both costly and inexpensive adjunctive services* or supplies, therefore, both a $5 and a $500 lab test could be packaged to a $100 office visit.

There is a brief discussion of calculations due to the factor that CLFS tests (no copay) are being bundled with OPPS services that do require a copay.

The corresponding regulatory changes state in part:

> **419.2**
> **(b)** [Packaged costs may include, but are not limited to:]
> (7) Ancillary services;
> (16) Certain clinical diagnostic laboratory tests;
>
> **419.22**
> The following are not paid for under the hospital outpatient prospective payment system (except when packaged as part of a bundled payment):
> **(l)** [el] Except as provided in 419.2(b)(16), clinical diagnostic laboratory tests.
>
> [This is remarkable drafting – "certain" CLFS tests are packaged under 419.2(b)(16) – look up which are these "certain" ones elsewhere in some notice or manual – and otherwise, CLFS tests are not packaged (419.22).]

Stakeholder Considerations include:

- It was impossible for me to tell how CMS will reallocate the costs of laboratory tests across the several hundred APCs, although the net price change per APC may be small since CLFS costs are only a few percent of the costs of patient care.[36] The total impact of the bundling changes is predictably "0" since costs no longer paid as line items will be allocated across APCs. (78 Fed

Reg 43692, Table 39). In Table 39, CMS calculates the impact of the CLFS APC packaging separately from all the other changes to APC bundling.

- It seems evident that the impact of the CLFS bundling would more heavily fall much more on some specialties, e.g. oncology and endocrinology outpatient clinics, than others.

- CMS would discourage lab-intensive visits from occurring in the OPPS setting and would encourage them to occur in the freestanding Part B setting where the laboratories would be paid as fee for service line items.[37]

- CMS' Date of Service rules and prior OPPS bundling for CLFS tests stated that if the patient went elsewhere for the blood draw or service, it was a non hospital service and payable to the lab. The new rule bundles payment if it is "provided" on the same day by the same provider as the hospital visit; it is not what should be the impact of this phrasing when the test is drawn elsewhere than the hospital but either on the same day or on the next day.[38] The existing OPPS regulation at 42 CFR 419.2 states that costs may be bundled when they are "directly related and integral to performing a procedure or furnishing a service." This is unproblematic for features like intraoperative nursing services or a tracer administered during a PET scan, but may bedevil the reader if a test is ordered on one day, blood drawn on another day, test performed in a third location, and so on, under which a patchwork of date of service and new bundling rules (in text, not regulation) converge on the service.

B. OUTPATIENT BUNDLING: FOR PATHOLOGY TESTS

PFS pathology tests are bundled in a more complex way than CLFS tests. The bundling is described along with 426 CPT codes categorized as "Ancillary Services" and formerly of Payment Category "X" under which each CPT code was crosswalked to a particular APC.[39] 116 of the 426 Category "X" codes begin with "8xxxx", thus, pathology codes. Of these, the most interest will be the bundling of surgical pathology codes and common surgical pathology sophisticated tests such as in situ hybridization and immunohistochemistry. All 426 services will be marked with payment classification "Q1" which means they will be bundled to any CPT code with classifier "S" or "T" or "V".

These are fairly simple categories:

- "S" – A procedure or service that is "not" discounted when multiple (668 of these)
- "T" – A procedure or service that "is" discounted when multiple (3517 of these)
- "V" – a clinic visit or an emergency department visit (16 of these)

Stakeholder Considerations include:

- To my reading, CMS provides no clear discussion of how these formerly paid pathology costs will be distributed among APCs.

- It would seem rational to distribute surgical pathology costs across biopsy and other surgical APCs, but there is no evidence of this.

- S,T,V APC rates range from $10 to $15,000. Each and any of the 426 "Q1" services seem attachable to any S,T, or V service that occurs on the same day.
    - Said differently, a breast biopsy which this year might have a $500 payment (CPT 19100, APC 0004) along with several hundred dollars of separately billed pathology services, including IHC and FISH, would in CY2014 have a payment very near to same $500 – but now inclusive of the several hundred dollars of pathology costs.
    - Alternatively, a patient coming to the hospital to make a urine sample for a FISH test falls into a $145 APC code (CPT 88120, CPT 0343), whereas if he is also given a glaucoma screen on the same day, the payment may plummet to a total of about $50 (the APC 698 for code G0117).
- The proposed system seems to set up a huge difference between some surgical procedures and others. For example, some series of diverse $500 APC procedures and services may be equally attractive to the hospital today. Next year, some of the procedures may become predictably and grossly unattractive, for example, those that require $500 or $700 of subsequent complex pathology services. These would not be slightly less attractive; they would be grossly and obviously money-losing. Since, I believe, the same system will not apply to Ambulatory Surgical Centers yet, it will be grossly more profitable to shunt surgical procedures associated with pathology services to ASC settings. Similarly, hospitals will be dramatically incented to perform imaging procedures on a different day that an associated surgery wherever possibly, or at a nearby but unaffiliated imaging center.

ENDNOTES

[1] 60 is one of only five known numbers which are "unitary perfect number" in which a very rare event occurs and the sum of the divisors (here, 1,2,3,4,5,6,10,12,15,30) yields the original number. (The other four unitary perfect numbers are 6, 90, 87,360, and 146,361,946,186,458,562,560,000.) 60 is also the number of carbon molecules in the spherical chemical fullerene and the number of edges on an icosidodecahedron. 60 was the base (base-60) of the Babylonian numerical system, and 60:1 is the ratio of kosher:nonkosher ingredients allowable in a kosher food. See: My Numbers, My Friends (P. Ribenboim, Springer, 2000, p. 352). As of September 2013, this book was #4,189,194 in Books on Amazon.com and had never been reviewed. The chapter "Galimatias arithmetica" discussing 60, and galimatias means "gibberish," a word that occurs almost nowhere except in Montaigne's Essay on Pedantry (1580).

[2] The number of services in the ~350 procedural APCs range from as few as one service (e.g. IMRT radiotherapy, APC 412 and CPT code 77418) to some 200 procedures in one code (e.g. APC 50, Level III Musculoskeltal procedures). (There are also several hundred APCs at #700 and higher that allow pricing for individual supplies or single drugs when these are paid separately.)

[3] This quotation has 175 google hits: See http://www.toptalent.in/blog/2013/06/07/7-movies-every-mba-should-watch/

[4] http://www.medscape.com/features/slideshow/sotu Quoting Truman: "We are rightly proud of the high standards of medical we know how to provide in the United States. The fact is, however, that most of our people cannot afford to pay for the care they need."

[5] http://www.haverford.edu/psych/ddavis/f_intdre2.html In chapter 6 of Interpretation of Dreams, Freud reports an 1899 dream where he was accused of debts for 1851 hospital bills. In another source, Freud describes a rich man who offers to pay a poor man's medical bills, and the poor man immediately insists on the highest standard of care possible, since someone else is paying. (I do not have the citation of the second anecdote at hand.)

[6] Reiser SJ (1978) Medicine and the reign of technology. Cambridge University Press.

[7] http://en.wikipedia.org/wiki/Anchoring

[8] I recall a few years ago that the media directly compared the price of a medication at Walgreens – where the drug is put in your pill vial in your hand in your neighborhood – with the bulk price of the same drug purchased wholesale by the V.A. system. The comparison makes no sense. The wholesale price of cartons out at a VA warehouse is far upstream of the final cost of running the VA pharmacy day to day and delivering a particular drug correctly to one patient, just like an apple on a truck in Ohio is far upstream of one on the grocery shelf. In the same way, gross sequencing chemistry costs for research purposes are far upstream of a delivered medical service.

[9] Hamburg MA & Collins FS (2010) The path to personalized medicine. NEJM 363:301-304.

[10] Collins FS (2010) The Language of Life: DNA and the revolution in personalized medicine. Harper.

[11] E.g. profit margins among hospices with longer and shorter average stays are discussed; see http://www.medpac.gov/chapters/Mar12_Ch11.pdf and http://www.medpac.gov/transcripts/hospice_January2013%20public.pdf . See similarly, "Home health firms ask CMS to ease pay cuts, MedPAC says they're too small." (Inside CMS, 8/29/2013.) Stating: "MedPAC, in its comments on the proposed rule, notes that [it]calculated home health margins at more than 17%."

[12] http://www.acla.com/sites/default/files/May%202013%20ACLA%20Hill%20Leave%20Behind.pdf

[13] Public financial statements are national laboratories such as Quest and Labcorp. See: Yahoo Finance, SeekingAlpha, or other readily available sources.

[14] Cost cutting trend in nation's clinical laboratories and pathology groups. Dark Daily, 8/28/2013 (trade journal); http://www.darkdaily.com/part-two-on-cost-cutting-trend-in-nations-clinical-laboratories-and-pathology-groups-how-innovative-labs-are-responding-to-falling-lab-test-prices#axzz2do4mS1YT

[15] http://protectmdx.org/cms-comment-letter/

[16] http://www.cap.org/apps/docs/statline/pdf/aetna_rate_cut_reprint.pdf (Lab Economics, April 2013, Reprint)

[17] http://oig.hhs.gov/oei/reports/oei-07-11-00010.asp

[18] 78 Fed Reg 43350 ff. (7/19/2013).

[19] http://www.nap.edu/openbook.php?isbn=0309072662 Medicare Laboratory Payment Policy, Now and in the Future, IOM, 2000.

[20] Those who are following the debate over correct or incorrect MAC gapfill pricing will note that CMS is flagging that it takes the spring MAC gapfill prices as correct at their reduced levels. Since the MAC medical directors reported new lower payment proposals, therefore, costs are lower.

[21] 78 Fed Reg 43350-51. 7/19/2013.

[22] For example, an investor may invest $10M in each of three products, expecting on average one to reach the market and repay $30M. This is covered in all basic finance and microeconomics textbooks as the return on investment weighted by technology risk. The same concept applies to drug development investments, where drug R&D would stop if each of the 5% of drugs that reach market only repaid its own direct lineage of development costs.

[23] See, e.g. EGAPP (committee, 2013) The EGAPP initiative: Lessons learned. Genet in Med (epub ahead of print).

[24] It is difficult to imagine how CMS would set the price of a particular staff member salary today, based on the same salary in 1984 and an assessment of changes in technology over the intervening 30 years.

[25] Kliff S (7/22/2013) Did you know the federal government thinks doctors can work 50 hour days? Washington Post. http://www.washingtonpost.com/blogs/wonkblog/wp/2013/07/22/did-you-know-the-federal-government-says-doctors-can-work-50-hour-days/

[26] Reinhardt U (12/10/2010) The little-known decision makers for Medicare physician fees. New York Times. http://economix.blogs.nytimes.com/2010/12/10/the-little-known-decision-makers-for-medicare-physicans-fees/

[27] Lowes R (8/14/2013). Study reveals how much procedures outpay office visits [per hour of physician work]. Medscape. http://www.medscape.com/viewarticle/809430 Citing: Sinksy CA & Dugdale DC (2013) Medicare payment for cognitive versus procedural care: Minding the gap. JAMA Intern Med (online 8/12/2013).

[28] Edwards HS (2013) Special Deal: The shadowy cartel of doctors that controls Medicare. Washington Monthly (July/August).
http://www.washingtonmonthly.com/magazine/july_august_2013/features/special_deal045641.php?page=all

[29] Recently, see letter from American Hospital Association to MEDPAC (March 7, 2013). http://www.aha.org/advocacy-issues/letter/2013/130328-let-pollack-hackbarth.pdf

[30] CMS notes that many commenters have asserted costs are generally lower in the physician office setting; citing MedPAC (p. 43296)

[31] However, CMS did propose other types of imaging cuts related to proposed new accounting rules: http://www.fiercemedicalimaging.com/story/acr-cms-must-avoid-payment-policies-will-curtail-reimbursements/2013-09-08

[32] http://www.cap.org/apps/cap.portal?_nfpb=true&cntvwrPtlt_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&cntvwrPtlt{actionForm.contentReference}=statline%2Findex.html&_pageLabel=cntvwr

[33] The table shown in this memorandum includes removal of Code 88120, which CMS originally proposed for a substantial rate reduction. According to CAP (7/22/2013), CMS included 88120 by error, because it does not meet the 5% hospital utilization criteria in current data.

[34] 78 Fed Reg 43570ff. "Proposed new packaging policies for CY2014."

[35] CPT code ranges 81200-81383, 81400-81408 (MAAA), and 81479 (unlisted).

[36] CMS states on p.91 of the early-release rule that they will "appropriately allocate the costs associated with packaging [CLFS tests.]" – with more detailed discussion at II.A.3.b(3). CMS notes on page 129 that "laboratory tests include about $18 per claim, a 0.1% increase." CMS also notes that the newly packaged services represent about 1% of costs (p. 663 of the early release rule) which seems compatible with the 2% proportion of all healthcare costs that are CLFS costs.

[37] CMS is antagonistic to the purchase of freestanding hospital practices by hospitals, after which, the same office may bill CMS for "outpatient" hospital visits at higher costs than paid in Part B alone. See MEDPAC (June 2013, Chapter 2, noting that "hospital" outpatient visits are growing at 10% per year due to purchase of physician practices; and this OPPS rule, where CMS proposes creating a new modifier for "remote" or "off campus" hospital outpatient clinic, e.g. reflecting the purchase of a suburban physicians' practice (p. 389 of the early release rule).

[38] "When they are provided on the same data of service [period]" – page. 172 of the early release rule – not stating "when they are provided on the same day of service AND by the same hospital [sic]."

[39] Ancillary Services is a 426-line page within Appendix "P" of the OPPS rule.