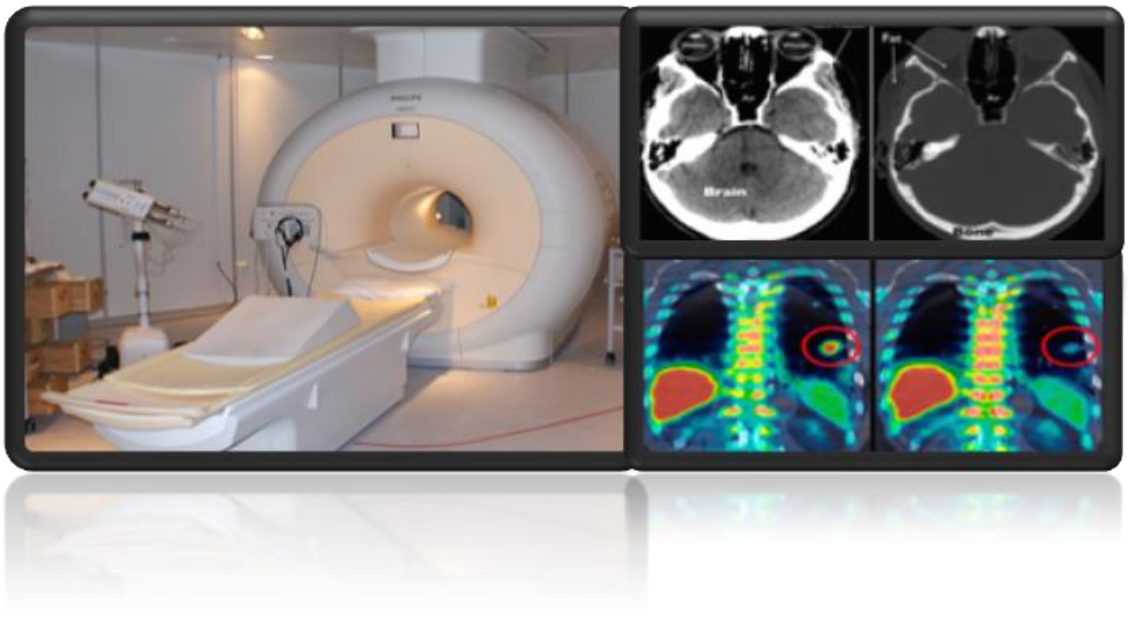
IMAGE VS REALITY



May 2016

Mercatus, CON, and Statistics in Search of Meaning

ASCENDIENT
Strategy • Planning • Feasibility

EXECUTIVE SUMMARY

Medical imaging has become the latest battlefield for economic theorists who mistakenly believe that the U.S. healthcare system is a typical marketplace in need of deregulation. Critics are now claiming that Certificate of Need laws (CON) have restricted access to imaging services, resulting in the need for patients to cross state lines.

Although the latest report is presented as a serious academic study, closer examination reveals a reveals a thinly veiled ideological attack on a regulatory framework that supports state efforts to manage cost and ensure adequate access to healthcare services for all citizens.

Among our major findings:

- Higher utilization of medical imaging is a dubious goal. More customers getting more scans might be good for a provider's bottom line, but there are no clear medical benefits for patients and very clear economic costs for the system as a whole. Small wonder, then, that physicians without a financial incentive are recommending fewer scans—not more.

- There is absolutely no proof that CON laws are restricting access to services. As a tool for measuring access, cross-border migration is a blunt instrument based on torturous logic. More direct measures, like available capacity, show no shortage of access.

- Imaging equipment in a hospital setting has about 10 times the productive output of a non-hospital setting. Due to their productivity, hospital providers can offer greater access to patients without unnecessary and redundant capital outlays.

- Factual data refute the theoretical expectation of "higher costs, a smaller selection of services, [and] lower access to care" in CON states. Because North Carolina is generally regarded to have one of the strongest CON laws in the country, the study's premise would indicate there should be significant access issues across the Tar Heel State—but an examination of the statistics shows that just the opposite is true.

In this paper, imaging services examined include Magnetic Resonance Imaging (MRI), Computed Tomography (CT), and Positron Emission Tomography (PET).

IMAGE VS REALITY

MERCATUS, CON, AND STATISTICS IN SEARCH OF MEANING

INTRODUCTION

> *"IT IS A TALE TOLD BY AN [IDEOLOGUE], FULL OF SOUND AND FURY, SIGNIFYING NOTHING."*
>
> *–MACBETH, ACT 5, SCENE 5*

A January 2016 article in the Wall Street Journal discussed the latest Mercatus Institute report criticizing the availability of diagnostic scans in states with Certificate of Need laws. Even more than the previous Mercatus attack[i] on Certificate of Need laws, which we called "a solution in search of a problem[ii]," this report[iii] is a lot of sound and fury that signifies almost nothing for healthcare consumers or the healthcare system as a whole. In discussing the availability of medical imaging in CON and non-CON states, the authors bandy about a lot of numbers, yet demonstrate no proof to support their premise:

- Zero proof that patients lack access to the imaging services they need
- Zero proof that imaging supply is inadequate to meet patient demand
- Zero proof that CON increases the cost of imaging services
- Zero proof that CON decreases quality outcomes

After a thorough analysis and examination of data, we can find exactly zero harm in the entire report—zero harm for patients (in the form of reduced access or reduced quality) and zero harm for payors (in the form of higher costs). That leaves only one other group to consider: non-hospital providers. In some states, non-hospital providers might consider themselves harmed if they find it more difficult to open an imaging facility. But we argue that there is no public harm in that situation. If CON regulations do not create access hurdles for patients or higher costs for payors, then additional providers and more imaging services will add no marginal value—at least, not on the demand side. (Of note, Medicare is moving toward site-neutral payment, which should eliminate any further argument regarding cost to the payor or patient.)

On the supply side, the value proposition is quite clear. Non-hospital providers in wealthy suburbs would invest in duplicative equipment and then cherry-pick the most lucrative patients, putting greater strain on public funding sources and the healthcare system as a whole. Perhaps there is an inalienable right to private profit at the expense of the public good, but that is a philosophical position that is best argued in philosophical terms, rather than hiding behind dubious data based on questionable assumptions.

THE WRONG SIDE OF HISTORY

"MORE IS MORE AND LESS IS A BORE."

– IRIS APFEL

Even a cursory reading of the Mercatus report reveals that the underlying political driver is all about *more*—at the very moment when secular trends, medical guidelines and economic pressures are all focused on *less*.

Fundamental to the Mercatus hypothesis is that higher utilization is better and thus public policies should encourage higher utilization. According to this hypothesis, the U.S. healthcare system needs more providers in more diverse settings billing for more scans.

Viewed through the lens of "more is better," it is easy to see why the repeal of CON laws would be so attractive to those who advocate for unbridled competition in healthcare. When it comes to medical imaging, the CON process is premised on the belief that excess capacity leads to unnecessary utilization and higher costs. Accordingly, regulators seek to balance supply and demand statewide—a process that might make it more difficult for niche providers to buy equipment based on hyper-local demand and short-term profitability.

With their broad array of services, "one-stop" convenience and integrated emergency departments, hospitals are often prime candidates for imaging equipment, which is viewed as mission critical. Then there are non-hospital imaging centers, which are often, though not always, run by groups of physicians as a for-profit enterprise. These non-hospital providers are free to apply for equipment under the CON process, and they are very often approved. (See p. 19 for actual numbers in North Carolina.) But sometimes they are not approved, and that rankles "free market" theorists who believe that more competition would drive down prices.

The problem is, ample evidence exists to show that physician-owned imaging centers tend to increase utilization, perhaps even unnecessary utilization, and thus drive up system costs—precisely the outcome that CON regulators work to prevent. MedPAC explicitly stated in a 2009 report: "Although the rate of growth slowed between 2006 and 2007, *there are reasons to be concerned that some of the increased use in recent years may not be appropriate*, [emphasis added] which contributes to Medicare's growing financial burden on taxpayers and beneficiaries."[iv] The MedPAC report goes on to cite numerous studies that have found that physician ownership in imaging centers or equipment is associated with higher volume. (See Sidebar 1.)

> "There are reasons to be concerned that some of the increased use in recent years may not be appropriate."
> –MedPAC, 2009

SIDEBAR 1: PHYSCIAN OWNERSHIP IN IMAGING CENTERS ASSOCIATED WITH HIGHER VOLUME

- A study by the Government Accountability Office (GAO) found that physicians in Florida who were investors in diagnostic imaging centers referred their Medicare patients more frequently for MRI, computed tomography (CT), nuclear medicine, and ultrasound studies than nonowners (GAO 1994). Some of the differences were dramatic: Imaging center owners ordered twice as many MRI scans and 29 percent more CT scans for their patients than nonowners. GAO also found that physicians who were members of practices that performed in-office imaging ordered studies more frequently than physicians who referred patients to outside facilities. For example, physicians with MRI machines in their offices ordered about three times as many MRI scans per 1,000 office visits as other physicians.

- Stanford researcher Laurence Baker found that patients of neurologists and orthopedic surgeons who owned MRI machines were more likely to receive an MRI scan within seven days of an office visit than patients of neurologists and orthopedic surgeons who did not own MRI machines (Baker 2008) … Acquiring an MRI scanner led to a 22 percent increase in the probability of ordering MRI scans by orthopedic surgeons and a 28 percent increase in the probability of ordering MRI scans by neurologists.

- A study of California workers' compensation cases concluded that self-referring physicians were more likely than other physicians to order medically inappropriate MRI scans (Swedlow et al. 1992). The researchers, who examined about 500 MRI scans, found that 38 percent of the scans ordered by physicians with an ownership interest in an MRI facility were determined to be inappropriate during a precertification review. By contrast, 28 percent of the scans ordered by physicians without such an ownership interest were found to be inappropriate.

Source: "Impact of physician self-referral on use of imaging services within an episode," Report to the Congress: Improving Incentives in the Medicare Program, June 2009, http://67.59.137.244/chapters/Jun09_Ch04.pdf

Note that there is little indication that patients are helped by all of this extra imaging. Indeed, while physician-owners are recommending more scans for their patients, the medical community overall seems to be moving in the other direction, due in part to concerns over excess radiation exposure.

So patients have nothing to gain from unregulated growth in medical imaging, either in terms of their wallets or their health. The only clear winners in this scenario are the non-hospital providers, particularly physician-owners, who are free to invest in unneeded equipment and then refer their patients for unneeded scans.

But here is the ultimate irony in the profit-driven Mercatus approach: The profit motive for private imaging providers is being quickly eroded by two powerful trends:

First, changing payment models will completely alter the economic calculus for imaging services. A scanner's profitability is only predictable if every scan results in a payment for that scan (the so called fee-for-service model). But the federal government is rapidly moving away from fee-for-service payments in favor of value-based models that discourage expensive and unnecessary services. This shift is happening extremely quickly: Medicare has set a specific goal that by 2018 half of all payments will be tied to alternative, value-based payment arrangements. (The goal for 2016 was 30 percent, and officials announced on March 4 that they have already surpassed that benchmark.) The bottom line is that healthcare providers who are clamoring for scanners today may soon find themselves stuck with pricey equipment that is increasingly difficult to monetize.

Second, demand for imaging is on a long-term decline. From the provider's standpoint, it is bad enough that patient care is no longer predictably profitable, but what if there are *fewer* patients to begin with? In October 2015, the *American Journal of Roentgenology*[v] examined claims for Medicare beneficiary Part B patients and found that national average spending on imaging peaked in 2006, then decreased 4.4 percent annually between 2006 and 2012. This decline occurred in all but two states—Maryland and Oregon, whose unique payment systems likely account for their contrary trends. What are the forces driving this historic trend? According to a 2011 study[vi] headed by David Levin, there are at least five factors at work:

- The Deficit Reduction Act of 2005 (DRA05) substantially cut reimbursement for private office advanced imaging, especially MRI and CT and "likely discouraged entrepreneurs from opening new imaging offices." (Note that DRA05 was only partly to blame, however, as growth also slowed in hospital-based facilities which were not affected by the law.)

- Concerns about exposure to radiation likely have affected physicians' thinking about how often they should refer patients for imaging procedures. (Again, this is only a partial factor as MRI has slowed as well, though it doesn't produce ionizing radiation.)

- Various physician specialty groups such as the American College of Cardiology and the American College of Radiology have issued more cautious criteria for imaging, even as physicians in general are increasingly aware of the need to control healthcare costs, contributing to fewer referrals.

- Payors are imposing growing restrictions on which physicians are paid for advanced imaging tests, putting particular strain on non-radiologist physicians in a position to self-refer.

- Though not applicable to Medicare patients, the rise of preauthorization programs among radiology benefit management companies likely has physicians thinking more carefully about when and whom to refer for imaging.

The Levin study can be summarized with one quote that points out the danger of overinvestment in imaging equipment by non-hospital providers: "the important reality is that imaging growth has decreased dramatically in recent years [1998-2008] and that this is a favorable development for our health care system."

In short, the Mercatus prescription for U.S. healthcare—more providers in more diverse settings billing for more scans—is truly on the wrong side of history and economics. Medical imaging is less and less popular even as payments are less and less certain. Non-hospital groups intent on tearing down regulation in favor of a "free market" are likely to find themselves financially crippled by the very competition they hope to unleash.

> "The important reality is that imaging growth has decreased dramatically in recent years…and that this is a favorable development for our health care system."
>
> – AJR 2011

THE DEVIL IS IN THE DETAILS

"NEVER LET THE TRUTH GET IN THE WAY OF A GOOD STORY"

– MARK TWAIN

It might be easy to get distracted by all the charts and statistical jargon in the Mercatus report, but scratching just beneath the academic sheen of the surface, we find the details are sparse at best and misleading at worst.

The authors summarize their work on p. 7: "This study is unique within the CON literature in that it simultaneously examines the quantity of services provided, the number of providers of services, and the access to services by consumers." Taking that claim on its face, we will analyze each aspect of this "unique" study to show why it is uniquely wrong-headed in terminology, assumptions and conclusions.

QUANTITY OF SERVICES

Our major objection: This is entirely the wrong terminology, because the authors are consistently making a case that is about location rather than quantity.

Again and again, the report refers to differences in "utilization" between CON and non-CON states, with the clear implication that residents in the CON states are not getting the vital imaging services that they need. For instance, on p. 20: "less imaging care for MRIs, CTs and PETs is provided in states with CON requirements."

That sounds like a fairly damning conclusion, and it's one that the critics of CON will likely trumpet for years to come (much like newspaper ads that proclaim a movie "hot!" when the reviewer actually said "hot mess"). Unfortunately for those critics, the accompanying tables don't actually show that CON status results in "less imaging care." They don't show fewer total scans for CON states. They don't show lower utilization overall. They only show that fewer services are delivered in a non-hospital setting.

> "The bottom line is that these results should not be interpreted without major caution."
>
> –Mark Holmes, PhD
> UNC Chapel Hill

To their credit, the authors *do* explicitly make that point ("The negative effect occurs only for scans provided outside the hospital"), but the nuance is easily lost, and the whole discussion can be extremely misleading for a casual reader. By using terms such as "utilization" and "less care," we believe that the authors are misrepresenting their own data. For the sake of accuracy and transparency, they should simply admit that the numbers are all about *where* and not about *how much*.

Does the *where* matter? Should we care that the residents of CON states get more of their imaging services from a hospital provider? If the CON requirement resulted in consistently higher systemic costs for imaging services, then maybe the answer would be yes. But the authors never assert any such harm, and the data suggest that exactly the opposite is true. According to Rosenkrantz, et al., among the 10 most expensive states for Medicare imaging, the vast majority are those without a CON requirement* (70 percent to 80 percent, depending on the year). Meanwhile, on the other end of the spectrum, CON and non-CON states are equally represented among those states where imaging spending is the lowest.

Table 1: Ten States with Highest Medicare Imaging Spending per Beneficiary in 2004 and 2012

Rank	2004		2012	
1	Florida	450.99	Florida	367.25
2	Nevada	432.95	New York*	355.67
3	New York*	415.52	Nevada	350.01
4	Delaware	378.33	California	283.37
5	Texas	351.42	Maryland	277.64
6	Arizona	345.02	Texas	273.84
7	California	340.30	Louisiana	261.04
8	Michigan*	339.30	Michigan*	245.77
9	Louisiana	332.06	Delaware	241.61
10	New Jersey	279.95	Mississippi*	225.11

Table 2: Ten States with Lowest Medicare Imaging Spending per Beneficiary in 2004 and 2012

Rank	2004		2012	
51	Vermont*	112.58	Ohio	67.08
50	New Hampshire*	121.98	Vermont*	72.78
49	North Dakota	141.86	Idaho	110.66
48	Oregon	147.56	Kansas	110.97
47	Wyoming	149.73	North Carolina*	115.53
46	South Dakota	150.47	North Dakota	121.50
45	District of Columbia*	151.53	Maine*	127.47
44	Montana	163.08	Hawaii*	128.10
43	Missouri*	164.79	New Hampshire*	132.31
42	North Carolina*	167.19	Utah	137.60

Reproduced from Rosenkrantz et al.
*States that require Certificate of Need for at least two of the three services studied in the Mercatus paper. Note: the District of Columbia was not identified in the Mercatus paper, but according to AHPA information, the District requires CON for MRI, CT, and PET.

Clearly the authors' bias in favor of non-hospital providers has nothing to do with costs, and absent any sort of statistical harm, this whole discussion is purely about philosophy. If you start from the belief that hospitals are somehow "bad" and private operators are intrinsically "good," then public policy ought to help more patients get served in a non-hospital setting. But if you believe that hospitals are the key component in an efficient, effective healthcare system, then cannibalizing their market for the sake of a few private operators makes no economic sense at all.

SIDEBAR 2: Q&A WITH MARK HOLMES, PHD, FACULTY MEMBER IN THE DEPARTMENT OF HEALTH POLICY AND MANAGEMENT IN THE UNIVERSITY OF NORTH CAROLINA GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH

Despite the appearance of academic rigor in the latest Mercatus report, the authors provide no information on the specifics of their "double-blind peer review." As with other Certificate of Need reports from Mercatus, there is no public evidence that this paper has been accepted and published by an academic journal. We reached out to an academic expert in health economics, Dr. Mark Holmes of the Gillings School of Global Public Health at UNC, for his objective review of the study and its conclusions.

Q: Do you agree with the findings and conclusions of the Mercatus Working Paper?

A: The main finding is not surprising—CON tends to lead to more hospital providers (HP) than non-hospital providers (NHP). But some of their headlines and conclusions are misleading or easily misinterpreted. For example, they conclude that "[t]he association of a CON regulation with non-hospital providers is substantial, ranging from -34 percent to -65 percent utilization for MRI, CT, and PET scans." The conclusion implies lower utilization, when there is not much difference in total utilization by patients for these services between CON and non-CON states as presented in Table 1. In fact, total CT utilization is higher in CON states than in non-CON states. In other words, in total, patients use these services about the same in both CON and non-CON states.

Comparison of Total Imaging Utilization in CON and Non-CON States	MRI	CT	PET
Hospital Claims per 1000 Beneficiaries - CON	123.89	432.47	14.17
Nonhospital Claims per 1000 Beneficiaries - CON	76.78	55.7	1.37
Sum of Total Claims per 1000 Beneficiaries - CON	*200.67*	*488.17*	*15.54*
Hospital Claims per 1000 Beneficiaries - Non-CON	110.5	409.09	12.54
Nonhospital Claims per 1000 Beneficiaries - Non-CON	95.58	73.54	3.79
Sum of Total Claims per 1000 Beneficiaries - Non-CON	*206.08*	*482.63*	*16.33*
Difference in Total Claims between CON and Non-CON States	-2.7%	1.1%	-5.1%

Their use of the percentage metric also generates seemingly "larger" effects. For example, in Table 1, Panel B, the difference in utilization of hospital providers between CON and non-CON states is a positive 23 points (432.47 – 409.09 = 23.38), which is a difference of five percent. The difference in utilization of non-hospital providers is numerically less, 17.84 (55.70 – 73.54 = -17.84), but because the numbers are smaller the percentage is higher, -24.3 percent. Similarly, the differences in PET utilization appear to be dramatic because a difference of 2.42 points on a base rate of 3.79 is over 60 percent.

Q: If the difference is not total use but where the use occurs, is there any valid argument in their analysis that more NHPs are better than HPs?

A: Actually, from an economic standpoint, the opposite is true. Table 6 in the paper focuses on number of providers, and the use per provider differs dramatically between HP and NHP. While the authors suggest there is decreased access to NHPs, HPs have at least ten times the per provider use as NHPs, regardless of whether they are in a CON state or not. In other words, one HP equals at least 10 NHPs in terms of output. So from an economic production standpoint, having more HPs is better than NHPs.

Comparison of Provider Utilization in CON and Non-CON States	MRI	CT	PET
Hospital Claims per 1000 Beneficiaries - CON	123.89	432.47	14.17
Average Hospital Providers per CON State	10.8	10.8	4.8
Average Utilization per Hospital Provider in CON States	11.5	40.0	3.0
Nonhospital Claims per 1000 Beneficiaries - CON	76.78	55.7	1.37
Average Nonhospital Providers per CON State	58.1	51.2	2.1
Average Utilization per Nonhospital Provider in CON States	1.3	1.1	0.7
Hospital Claims per 1000 Beneficiaries - Non-CON	110.5	409.09	12.54
Average Hospital Providers per Non-CON State	11.8	12.4	4.9
Average Utilization per Hospital Provider in Non-CON States	9.4	33.0	2.6
Nonhospital Claims per 1000 Beneficiaries - Non-CON	95.58	73.54	3.79
Average Nonhospital Providers per Non-CON State	77.2	66.4	5.3
Average Utilization per Nonhospital Provider in Non-CON States	1.2	1.1	0.7

Production, or output, per hospital provider is much greater than per nonhospital provider.

Q: The authors also conclude that "patients living in CON states have to travel out of state more often than patients living in non-CON states." Do you agree with this conclusion?

A: We know that border crossing for healthcare is bigger in some states than in others. For example, New England has more border crossing, as do areas with large metropolitan regions near state borders. In North Carolina, for example, many residents in the northeastern part of the state travel to the Norfolk, Virginia metropolitan area for healthcare. Likewise, many patients in the Rock Hill area of South Carolina cross over to the Charlotte metropolitan region for care. Because CON is more common in states where border crossing is a factor, a "falsification test" to analyze a factor that should not be affected by CON, like ED utilization, would be helpful in assessing whether or not CON is really the driver of out-of-state imaging utilization.

Studies such as this must be careful about drawing conclusions about causation from mere correlations. To show the danger in drawing such conclusions, I calculated the percent of each state's workforce that works in another state from the Census Journey to Work data for 2009-2013. I then analyzed that data with the PET CON classification from the Mercatus report and determined that 5.2 percent of residents in states with PET CON work out of state, while only 3.2 percent of residents do in states without PET CON. A false conclusion would be that CON for PET increases the probability of working in another state by 2.0 percentage points. Clearly, PET CON is not causal relative to the percentage of residents who work out of state. Rather, these states have high connectedness to other states for reasons other than CON, and those reasons are likely a major driver of the differences in Table 7.

Q: Are your comments just the result of typical disagreements between academics, or are there more serious issues with the study itself?

A: I believe that studies like this have to be careful about explicit or implicit conclusions about causation. The casual reader of this paper may reach conclusions that are not supported by any definitive evidence or data, and for which there may be other causative factors at play. Though most of my concerns involve their interpretation of the study results, I do have a few concerns about the study and how it was designed.

Q: Can you give us any examples that a non-statistician or non-academic could understand?

A: For one, the dataset they start with is individual Medicare claims data. That means that they had access to a lot of information on each individual patient—information like age, race, co-morbidities—data points that could affect demand for imaging. Rather than using that individual data, they made a lot of adjustments to get to state-level averages. In my opinion, the cleanest approach would have been to use the individual data, which would have allowed them to control for those individual variables that may affect utilization and cost.

Another problem with the use of the state-level data is that the ability to control for other state factors is limited. Without getting into too much jargon, there are rules of thumb for how many observations one should have per regressor (variable). For example, textbooks typically suggest 10 to 20 observations per variable. I, personally, usually look for at least 20. If you look at Table 2 in the Mercatus report, models 4 and 8 have 51 observations (50 states, plus the District of Columbia) for 12 variables (e.g., CON requirement, average age, etc), or about 4 observations per variable.

Q: What does that mean for these results?

A: It means this model is at a high risk for overfitting, which means the results can be misleading because the model is too complicated for the size of the dataset. The bottom line is that these results should not be interpreted without major caution.

Mark Holmes, PhD, is an Associate Professor and Associate Chair for Research in the Department of Health Policy and Management in the University of North Carolina Gillings School of Global Public Health. He received his PhD from the Department of Economics at UNC-Chapel Hill. His interests include hospital finance, rural health, and health policy. He is also a Senior Research Fellow and the Co-Director of the Program on Health Care Economics and Finance at the Cecil G. Sheps Center for Health Services Research.

NUMBER OF PROVIDERS

Our major objection: This is entirely the wrong assumption, because more isn't necessarily better when it comes to imaging providers.

It's not at all surprising that CON states would have fewer imaging providers than non-CON states. After all, the entire point of the CON process is to ensure that providers don't end up marketing unneeded services simply because they invested in costly and unnecessary equipment. If CON laws were *not* limiting the raw number of providers, then something would be wrong, indeed.

Hospital providers offer greater access to imaging services because their output is roughly 10 times greater than non-hospital providers.

So why would this study make a point of counting providers? Presumably the authors are trying to make a point about access: CON states have fewer providers, and therefore the residents of those states must have less access to services.

The problem with that argument is that the sheer number of providers is largely irrelevant when it comes to measuring access. To take a transportation example, you would never measure a city's accessibility by the raw number of planes landing at the airport. Ten private aircraft are not "better" than five commercial jets, because the commercial jets are much more productive in economic terms—they offer more access to more passengers, despite their lower numbers.

By the same token, statistics show that hospital providers offer greater access to imaging services, because their output is roughly 10 times greater than non-hospital providers. Take MRI for instance: in CON states, the average utilization per hospital provider is 11.5, compared to 1.3 for non-hospital providers (measured by the claims per 1,000 beneficiaries per average number of providers per state as reported by Mercatus). The same holds true in non-CON states (average utilization of 9.4 for hospital providers and 1.2 for non-hospital providers). Keep in mind that a number of the scans are performed on hospital inpatients for which an outside option would be impractical.

So hospital providers are the Boeing 737s of the medical imaging world, while non-hospital providers are the Learjets. Due to their higher productivity, hospital providers can offer greater access to patients without unnecessary and redundant capital outlays. At a time when spiraling healthcare costs are a national priority, it simply makes no economic sense to argue for a *less* efficient delivery system for medical imaging.

Besides productivity, the authors ignore proximity, another key measure that would give a better indication of patient access to medical imaging services. Proximity is about the distribution of providers relative to the population, i.e., what percentage of state residents live within *X* miles of an imaging machine. Ten providers clustered in a single urban area might well provide *less* overall access than six providers spread more evenly across a state.

CON laws are specifically designed to prevent this kind of clustering. Regulators take a macro, statewide view of supply and demand, helping to ensure that all residents have ready access to needed services. The process is much more sophisticated—and much fairer—than simply conducting a quick supplier

headcount. (For example, see p. 18 for our discussion of Positron Emission Tomography (PET) distribution in North Carolina.)

So once again, the authors prove statistical significance in an area that has no practical significance—the number of providers. By making the wrong assumption—that more is better—they hint at a harm that simply doesn't exist.

CONSUMER ACCESS TO SERVICES

Our major objection: This is entirely the wrong indicator, because border crossings are no way to measure healthcare access issues.

The most data-intensive section of this study is also the most perplexing. By comparing Medicare records with Census results, the authors cite evidence that residents of CON states are more likely than residents of non-CON states to travel across state lines for an MRI, CT or PET scan. Why would that be? The authors have a ready explanation: "The propensity for residents of CON states to travel out of state to obtain medical services can be attributed to any of several factors: higher costs, a smaller selection of services, or lower access to care." (p. 20)

This is what we like to call the pickle fallacy, because using out-migration as a measure of access is like using pickle sales as a measure of pregnancy rates. Yes, pregnant women may buy more pickles, but a spike in pickle sales could have a dozen alternative explanations that are far more plausible than rising pregnancy rates.

If patients seem to be taking a difficult route to reach their imaging providers, the authors are taking an even more circuitous route to reach their logical conclusions. To start out, they "hypothesize that CON requirements affect the consumer's ability to obtain services." But then, instead of measuring obviously relevant variables such as distance to the nearest imaging center or local utilization rates, they construct an elaborate, three-point justification for measuring travel across state lines (p. 7):

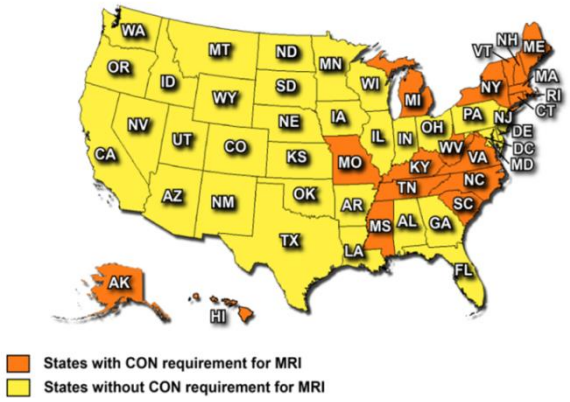
1. "[L]ocal providers *may* be prevented from offering imaging services"
2. "[P]roviders in CON states *may* be more difficult to schedule"
3. "[T]his difficulty *might* also induce patients to travel to other providers"

In each case we have added emphasis to highlight the speculative nature of the argument. And in each case, the authors present **zero** evidence to back up any of their speculations. Instead, they arbitrarily lay their foundation of *may's* and *might's,* then build a three-story house of cards to explain why residents of CON states seem to flee across state lines when they need medical imaging.

The problem is, the authors' own data seem to refute this "weary traveler" scenario. If CON were truly limiting access to imaging services, then patients would have to travel *outside* the "CON zone" to escape the limitations. For example, a Vermont patient struggling to schedule an MRI couldn't simply visit New Hampshire, Massachusetts or New York, because all of those neighboring states also require a CON for MRI services (and thus would present exactly the same access barriers as Vermont). To circumvent these purported barriers, our Vermont patient would have to travel all the way to New

Jersey or Pennsylvania, the closest states without CON requirements. Similarly, a North Carolina MRI patient would have to travel to Maryland or Georgia to receive MRI services in a non-CON state.

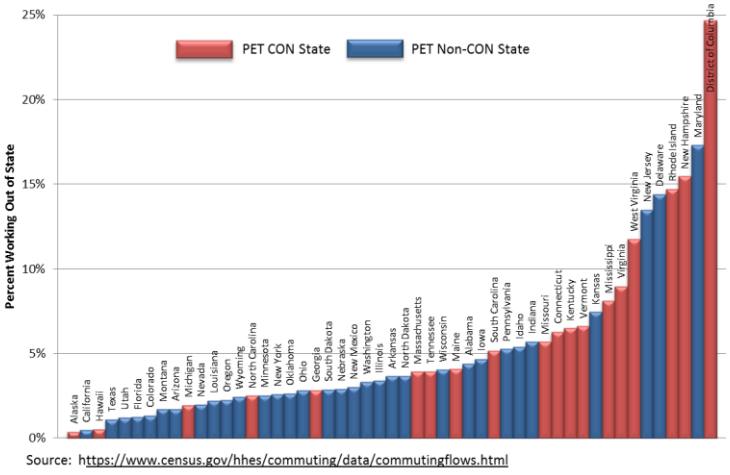
Figure 1: MRI CON Requirements by State



But all of these CON refugees flooding into the nearest non-CON state would certainly lead to systematically higher utilization rates for those states—and the data simply do not support that outcome. In fact, the data specifically show there is *no significant difference overall in utilization rates between CON and non-CON states*. Not for CT. Not for MRI. Not for PET.

Still, it's hard to argue that residents of CON states appear to travel out-of-state with relatively greater frequency. If that's not due to access barriers created by CON regulations, then what *would* explain the statistical difference? Armed with a map and Occam's Razor ("*Among competing hypotheses, the one with the fewest assumptions should be selected*") it's easy to come up with a more satisfying explanation: geography. On the East Coast, where CON predominates, states are more densely populated and more "connected" in terms of commuting patterns. As discussed in Sidebar 2 and illustrated in Figure 2, if you reside in a state where CON is required for PET services, you are more likely to work outside your home state. The CON law isn't *causative* here—regulations aren't forcing you out of state for work, nor are they forcing you out of state for medical care. Instead, CON laws correlate strongly with denser populations and more fluid commuting patterns.

Figure 2: Work Commuting Patterns in PET CON and Non-CON States



Source: https://www.census.gov/hhes/commuting/data/commutingflows.html

For political and philosophical reasons, this study begins with the assumption that out-migration is driven by hardship, but it's far more likely a simple matter of habit. Residents in the "CON zone" are more likely to cross state lines for work and shopping and entertainment, so why not for healthcare, too? With page after page of narrative and charts related to out-of-state healthcare patterns, it's clear that the authors believe they have found their smoking gun.

The CON law isn't causative here—regulations aren't forcing you out of state for work, nor are they forcing you out of state for medical care. Instead, CON laws correlate strongly with denser populations and more fluid commuting patterns.

But on closer examination, it looks a lot like a pickle.

CON IN PRACTICE VS CON IN THEORY

"A THEORY MUST BE TEMPERED WITH REALITY."

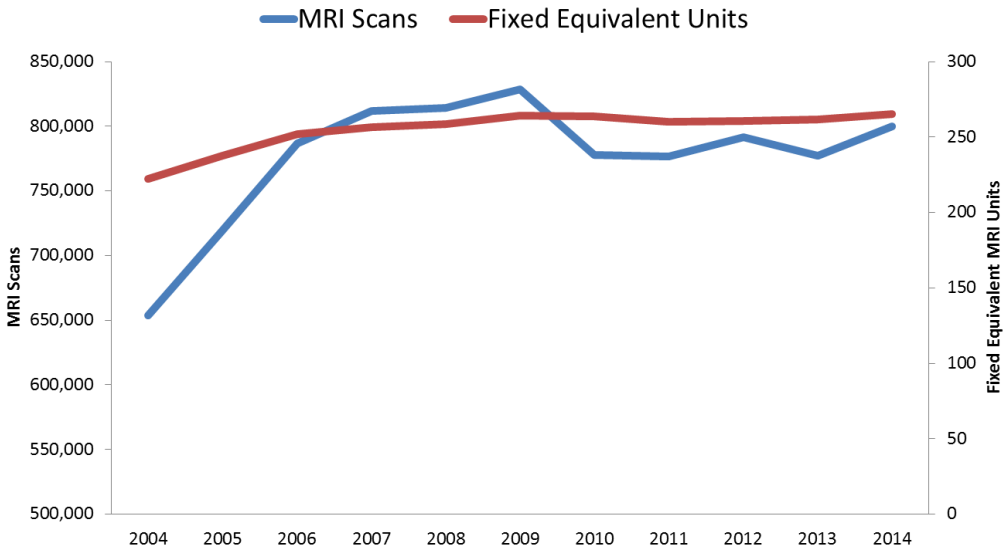
– JAWAHARLAL NEHRU

As we have discussed, the latest Mercatus study employs lots of shaky statistics and questionable logic to suggest that CON laws leave state residents unable to access the imaging services they desperately need. Indeed, the authors go to great lengths to make their case that CON laws turn patients into medical refugees, fleeing across state lines in order to find unregulated imaging services.

But such statistical innuendo is completely unnecessary. One benefit of CON is that the application process generates reams of real-world data on healthcare availability and access. If the law creates barriers, as critics suggest, then those barriers would be highest where the laws are strongest. Since North Carolina is generally regarded to have some of the strongest CON laws in the country, we would expect to find "higher costs, a smaller selection of services, [and] lower access to care" rampant across the Tar Heel State. Unfortunately for critics, the actual statistics don't show any such thing.

Magnetic Resonance Imaging (MRI): North Carolina's MRI volume trends have mirrored, while lagging, the national trend data. As noted previously, major imaging spending for Medicare beneficiaries peaked in 2005/2006 for most states. Volume for all patients in North Carolina peaked in 2009 at about 830,000 procedures, which represented 55 percent of capacity for that year.

Figure 3: NC MRI Volume and Capacity Trends



North Carolina first inventoried MRI scanners in the 1997 State Medical Facilities Plan (SMFP) based on data from 1995. At that time, there were 67 existing fixed MRI scanners approved and/or operating—mostly located on hospital sites. Not surprisingly, most of the scans performed in 1995 were performed on hospital-affiliated scanners.

Figure 4: NC Fixed MRI Units, 1995

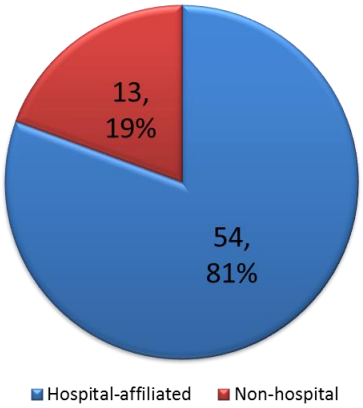
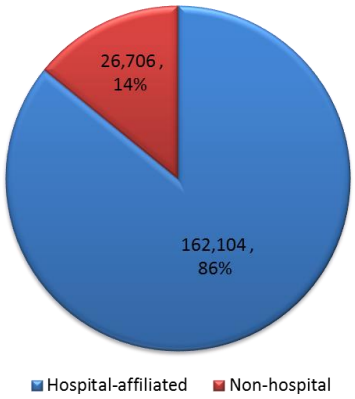


Figure 5: NC Total MRI Scans, 1995



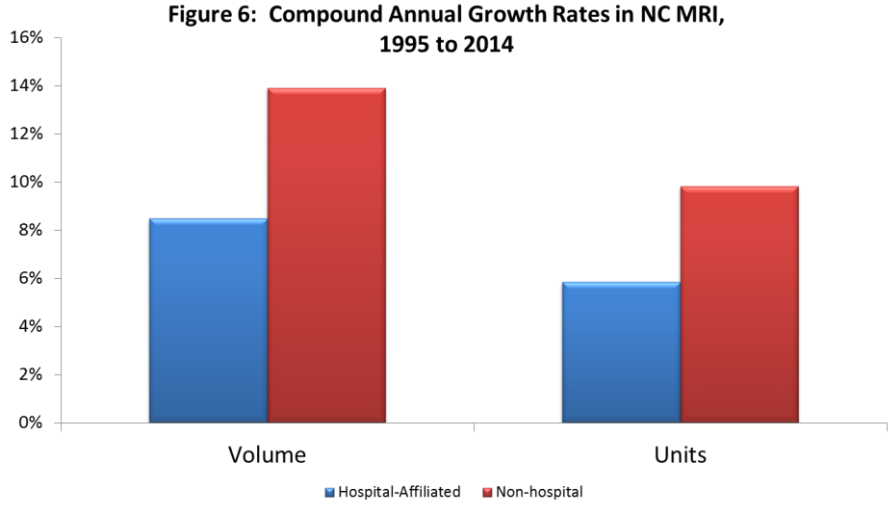
Since the initiation of an MRI need methodology in the 1999 SMFP, however, there have been need determinations for 143 fixed MRI scanners in the state, not including at least six demonstration projects for specialty MRI scanners.

SMFP Year	Fixed MRI Need Determinations
1999	7
2000	8
2001	10
2002	18
2003	23
2004	11
2005	19
2006	6
2007	7
2008	11
2009	10
2010	2
2011	3
2012	0
2013	0
2014	3
2015	1
2016	4
Total	143

It should be noted that the SMFP need methodology regularly kept pace with the growth in MRI volume through the peak in 2009. Since the drop in volume that began in 2009, the number of MRI need determinations has followed suit, indicating the ability of the health planning and CON process in North Carolina to adapt to changing demand such that supply appropriately matches demand.

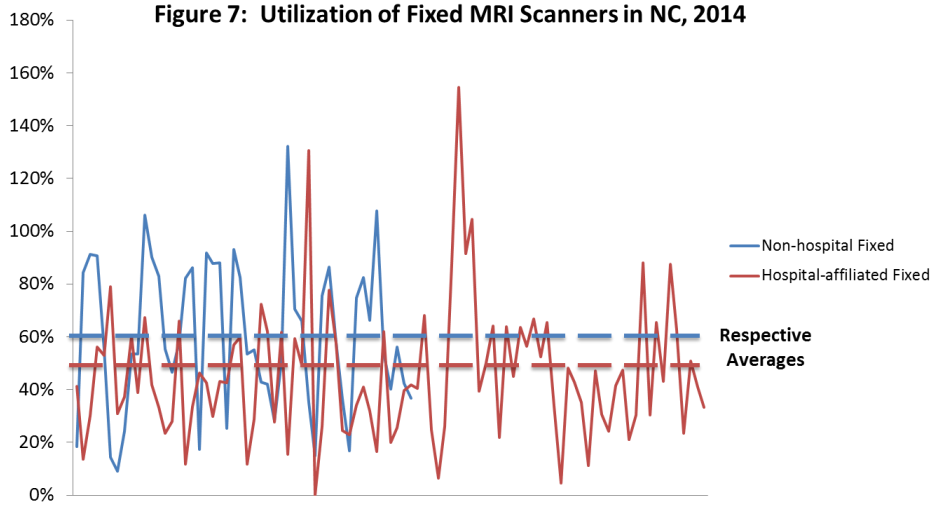
Although the number of new MRI units has ebbed and flowed in response to demand, another trend has been more consistent: Since the initial 1995 data, the growth rate in non-hospital MRI units has nearly doubled the growth rate of hospital-affiliated scanners, and the volume of scans has followed a similar pattern.

Figure 6: Compound Annual Growth Rates in NC MRI, 1995 to 2014



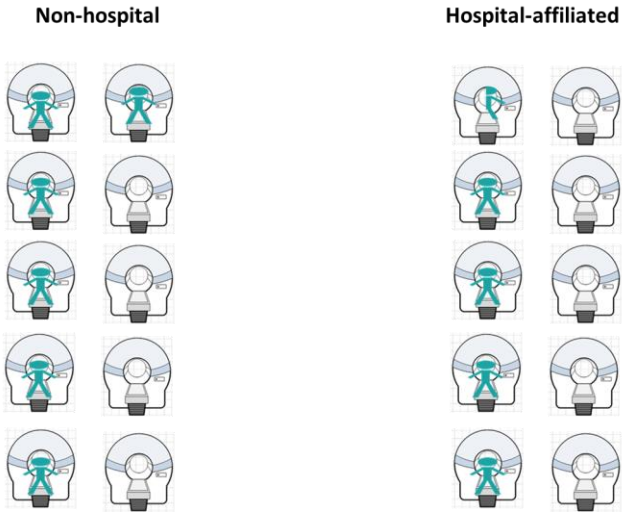
So where do we stand today? A detailed examination of 2014 utilization, particularly of the fixed scanners across the state, reveals that plenty of capacity is available for access by patients—both at hospital-affiliated and non-hospital centers. The chart below shows that the utilization of non-hospital scanners ranges from a low of 9 percent of capacity to a high of 132 percent of capacity, with an average of 60 percent. Similarly, the utilization of hospital-affiliated fixed scanners ranges from a low of 0 percent of capacity to a high of 154 percent of capacity, with an average of 46 percent.

Figure 7: Utilization of Fixed MRI Scanners in NC, 2014



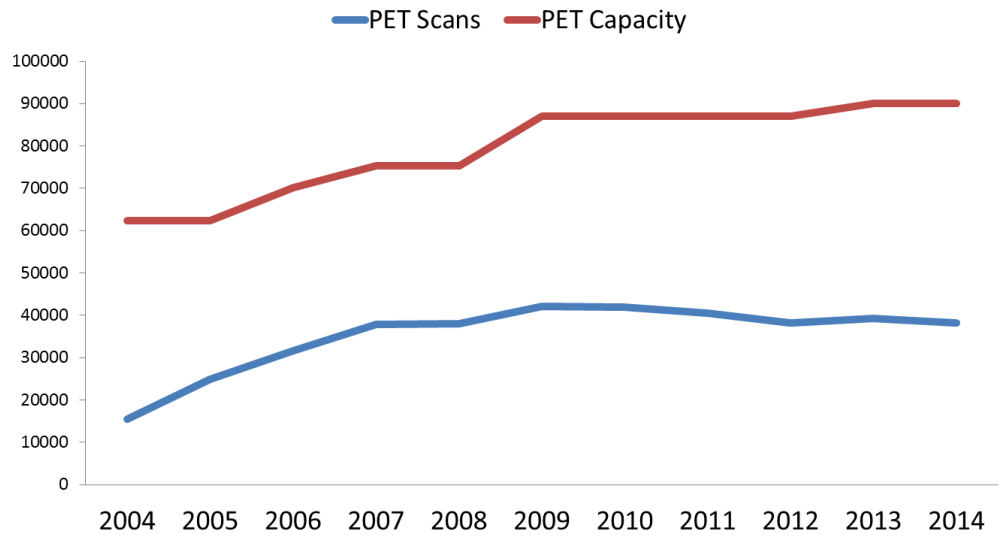
In other words, on any given day in North Carolina, four out of 10 non-hospital and more than five out of 10 hospital-affiliated fixed MRI scanners are available for use. There is simply no way to argue that CON regulations are impeding patient access or creating barriers. Likewise, the numbers clearly do not show any "shortage" of availability in non-hospital MRI services, which undermines the Mercatus contention that CON is "squeezing out" patients who might prefer a non-hospital supplier. There is absolutely no "free market" case for increasing capacity for a service that is currently operating at 50 to 60 percent of capacity.

Figure 8: Utilization of Fixed MRI Scanners in NC, 2014



Positron Emission Tomography (PET): When it comes to PET scans, we see the same general trends in demand. PET demand peaked in 2009 at 42,127 scans, which represented 48 percent of capacity available at that time. Since the peak in 2009, demand has declined by 1.9 percent per year. Thus, as of 2014, more than half of the state's total PET capacity remains available.

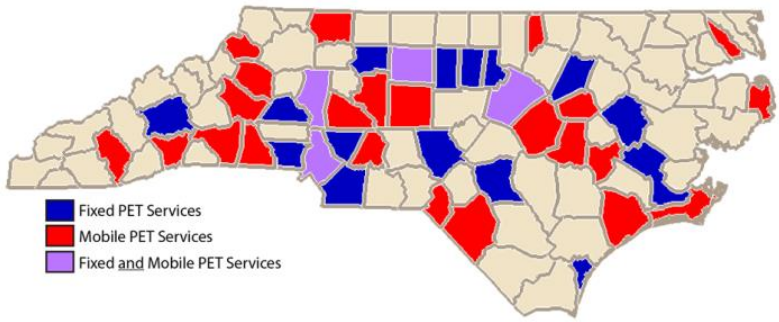
Figure 9: NC PET Volume and Capacity Trends



Note: PET scanner capacity was increased to 3,000 scans per unit per year in 2009.

This overall lack of utilization is not due to access issues created by geography. As a result of the mindful allocation of PET scanners by the SMFP methodologies, the scanners are distributed reasonably across North Carolina, as illustrated by the map and table below. The more metropolitan, densely populated HSAs are served mostly by fixed scanners (II, III, IV), while the broader, more rural HSAs are served by fixed scanners that are supplemented by mobile sites (I, VI).

Figure 10: North Carolina PET Sites of Care



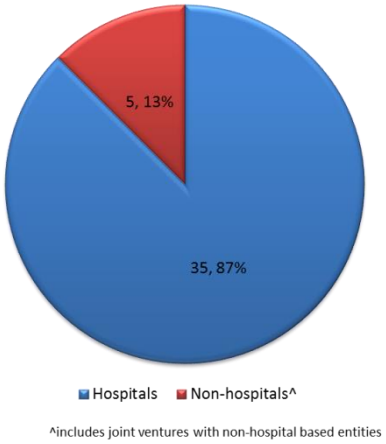
HSA	Fixed PET Scanners	Mobile PET Sites (2014)	2014 Population Estimates
I	2	8	1,424,339
II	7	4	1,655,926
III	7	5	2,078,052
IV	6	3	1,951,586
V	3	2	1,417,116
VI	3	7	1,426,668
Total	28	29	9,953,687

The figures above make it clear that no North Carolinian is *forced* across state lines in search of a PET scanner that is accessible and available—and the CON process of equitable distribution is specifically responsible for that fact.

As a result of the mindful allocation of PET scanners by the SMFP methodologies, scanners are distributed reasonably across North Carolina.

Unlike MRI units, PET scanners in North Carolina are rarely found in a non-hospital setting, and ideological critics argue that disparity is due to unfair regulation. But the numbers suggest otherwise. Since 2001, there have been 20 CON reviews for fixed or mobile PET scanners, and of those, only 12 were considered competitive (meaning more than one applicant for the number of scanners allocated). Out of 40 total applicants in the past 15 years, only five have been non-hospital based entities (including joint ventures).

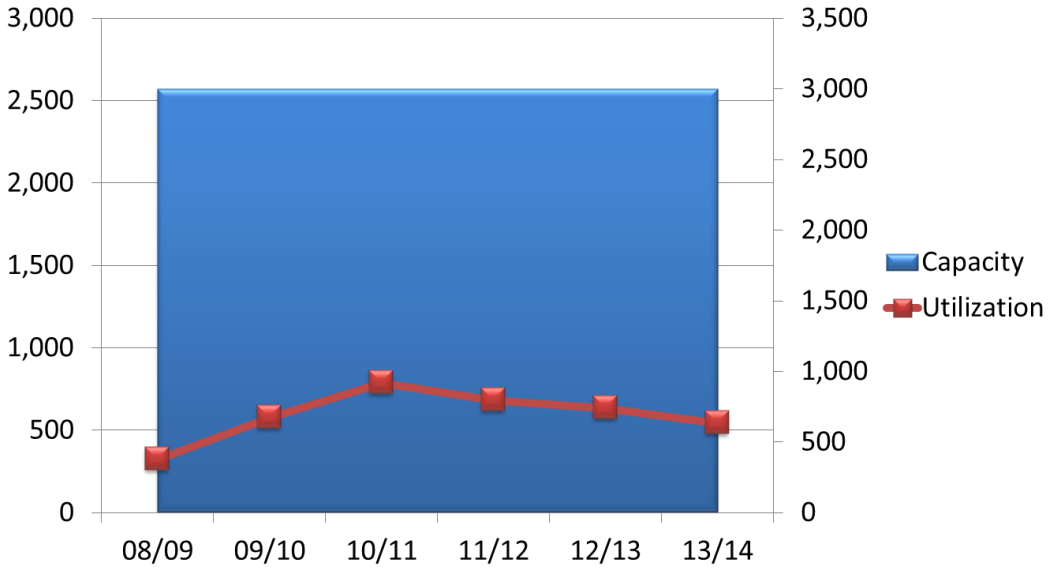
Figure 11: NC PET CON Applicants



Of the five non-hospital based entities, 60 percent had their applications approved, so it's hard to argue that the CON process systematically discriminates against anyone looking to open a non-hospital PET center. But what about more subtle forms of discrimination? Some critics (including Mercatus) argue that non-hospital providers don't bother to apply for PET CONs because they know that they don't stand much chance of approval. But here's another possibility: They don't apply because *they don't stand much chance of making money*.

With its relatively wealthy, educated population, Wake County and the capital region should be fertile ground for non-hospital imaging services, so it's no wonder that Wake PET Services has been operating since 2008 as a non-hospital provider, with a total annual capacity of 3,000 scans. But over the last six reporting years, volume at Wake PET peaked at just 26 percent of capacity in 2010-11, while the hospital providers in the same region—Duke, Rex, and UNC—have experienced utilization rates as high as 75 percent of capacity.

Figure 12: Wake PET Services Capacity and Utilization Trends



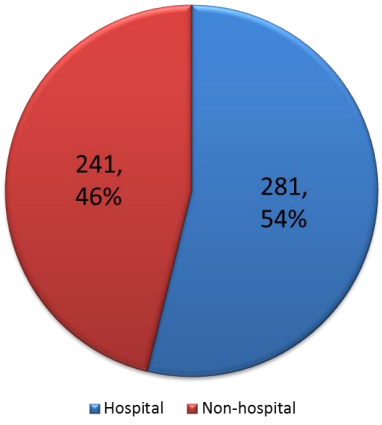
And once again, actual utilization numbers undermine the idea that non-hospital PET centers have been blocked by the CON process. Far from a conspiracy, this is an illustration of market forces at work. Most non-hospital providers understand that PET scanners are not high-margin investments: the equipment is expensive; operational costs are high; other barriers exist, such as licensure requirements to handle radioactive materials; and PET scans are usually offered as integral components of other cancer-related services. As long as overall utilization rates hover at less than 50 percent, any notion of a PET shortage is hard to take seriously.

Computed Tomography (CT): It is difficult to discuss state-level numbers for CT procedures because the Mercatus study incorrectly classifies North Carolina as a CON state for CT. (Admittedly, the authors were limited by the binary definition of CON employed by the American Public Health Association (APHA), but a more careful study might have accounted for the limitations of the source data.)

Unlike MRI and PET, CT scanner acquisitions in North Carolina are not *per se* reviewable by statute. Rather, the circumstances of any particular CT acquisition may trigger a CON review, but that happens relatively rarely. In fact, although there are roughly 500 CT scanners in the state, since 1994 there have been only 50 or so CON applications filed for such equipment and none since 2012.

Although there is no inventory of CT scanners maintained in the SMFP, the N.C. Department of Health and Human Services' Division of Radiation Protection does maintain information on CT scanners operating in the state. According to their data, there are at least 500 CT scanners being used for healthcare related purposes. (The Division's database also includes CT scanners operated by dentists, veterinarians, and educational institutions.) According to their database, as of spring 2016, there are about 280 CT scanners located in hospitals and another 240 CT scanners in "physician" locations which includes physically freestanding centers (regardless of ownership) and physician offices.

Figure 13: NC Healthcare Related CT Units, 2016



Combined, these data affirm that many providers are able to acquire CT scanners in North Carolina without a CON. Thus, CON cannot be the reason that more CT procedures performed in a hospital setting vs. a non-hospital setting in North Carolina—if in fact such a disparity even exists.

CONCLUSION

"THERE IS NO THERE THERE."

– GERTRUDE STEIN

For all its pretentions of academic objectivity, the latest CON report from Mercatus seems even more political than its predecessors—and even less substantive. Every argument starts with the assumption that hospitals are the big, bad wolf because CON regulations are designed to protect them from competition. Viewed through that lens, everyday commuting patterns might indicate a mass exodus and everyday utilization patterns might indicate a conspiracy.

But without that lens, almost nothing in this report makes sense. Leaps in logic defy gravity. Multiple regressions are undermined by multiple assumptions. Statistics are used to prove a point without proving any harm.

At Ascendient, we don't view hospitals as some sort of sinister big, bad wolf, colluding with regulators to squash the threat of competition. Instead, we believe that financially stable hospitals are an integral part of an effective and efficient healthcare system—a system designed for patients rather than profit. In a mobile, affluent society, there will always be broad competition in healthcare, and that's a good thing. But competition that is narrowly focused on a few high-margin services and high-value customers is bad for the healthcare system as a whole, because it forces providers to raise the price tag for other, less profitable services, resulting in higher costs for everyone. If CON laws can help to protect patient access, rationalize competition and keep overall costs down, we believe that's a good thing. Further, we believe our views are supported by logic, unlike those of a $14 million anti-regulation think tank.

But even for an observer with no strong views one way or the other, a *prima facie* reading of this report is likely to elicit grave doubts. It doesn't take statistical acuity or strong political views to recognize illogical assumptions and invalid conclusions. Strip away the academic style of this report, and the substance looks embarrassingly thin. Shakespeare and Stein got it right: Sometimes, despite all the sound and fury, there is simply nothing there.

[i] Koopman, C. and Stratmann, T., "Certificate-of-Need Laws: Implications for North Carolina," Mercatus on Policy, Mercatus Center, George Mason University, February 2015.

[ii] "First, Do No Harm: Analyzing the Certificate of Need Debate in North Carolina," Ascendient Healthcare Advisors, July 2015.

[iii] Stratmann, T. and Baker, Matthew C., "Are Certificate-of-Need Laws Barriers to Entry? How They Affect Access to MRI, CT, and PET Scans." Mercatus Working Paper, Mercatus Center, George Mason University, January 2016.

[iv] "Impact of physician self-referral on use of imaging services within an episode," Report to the Congress: Improving Incentives in the Medicare Program, June 2009, http://67.59.137.244/chapters/Jun09_Ch04.pdf.

[v] Rosenkrantz, A.B., Hughes, D.R., Duszak, Jr., R., "State Variation in Medical Imaging: Despite Great Variation, the Medicare Spending Decline Continues," American Journal of Roentgenology, 2015; 205:817-821.

[vi] Levin, D.C., Rao, V.M., Parker, L., Frangos, A.J., Sunshine, J.H., "Bending the Curve: The Recent Marked Slowdown in Growth of Noninvasive Diagnostic Imaging," American Journal of Roentgenology, 2011; 196:W25-W29.

ASCENDIENT

Ascendient is a Top 50 healthcare strategy, planning and feasibility firm with offices in Chapel Hill, North Carolina and Washington, D.C. Since its founding in 1994, the firm has offered fresh approaches and innovative solutions to clients in both the public and private sectors. Working exclusively with health and healthcare organizations, Ascendient is dedicated to helping its clients envision and embrace a transformed future that will fundamentally alter every corner of the industry. www.ascendient.com