

**Petition by Pinehurst Surgical Clinic for Special Need Adjustment for Operating
Rooms in Lee County**

PETITIONER:

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STATEMENT OF REQUESTED ADJUSTMENT:

Pinehurst Surgical Clinic (“PSC”) respectfully petitions the State Health Coordinating Council (“SHCC”) to create an adjusted need determination for two additional operating rooms in the Lee County, North Carolina Operating Room (“OR”) service area in the *2022 State Medical Facilities Plan*. This petition has garnered significant support from physicians and other community members. See **Attachment A** for all letters of support.

BACKGROUND AND OVERVIEW

Pinehurst Surgical Clinic is an existing, multi-specialty surgical group practice that has been a stalwart provider of surgical services in the Pinehurst, Moore County, North Carolina community and surrounding communities since 1946. PSC has 47 active board-certified physicians, 37 mid-level providers, and a professional staff of over 400. PSC offers a number of services, including a Women's Care Center and a Urological Surgical Center. Historically, PSC has served a significant number of surgical patients from Lee County. In recent years, PSC has recognized a need for greater access to surgical services, particularly outpatient surgery, for its patients who reside in Lee County.

There has historically been one hospital provider of surgery services in Lee County: Central Carolina Hospital (“CCH”). According to its last LRA, this hospital reports a total of six general purpose ORs that were available and recognized in the SMFP. With these six ORs at CCH, there has been a long-standing surplus of ORs in Lee County. The Draft 2022 SMFP Table 6B shows a surplus of 4.15 ORs. Previous SMFPs reflected surpluses of more than 2 ORs the 2018-2021 SMFP; see **Exhibit 1** below.

Exhibit 1
Lee County Summary of OR Utilization

	2018 SMFP FY2016	2019 SMFP FY2017	2020 SMFP FY2018	2021 SMFP FY2019	2022 Draft SMFP FY2020
Central Carolina Hospital (Lee)					
OR Inventory	6	6	6	6	6
Projected Surgical ORs Needed	3.90	3.18	3.36	3.29	1.85
Projected OR Surplus	-2.10	-2.82	-2.64	-2.71	-4.15

Source: 2018-2021 SMFP

These calculations demonstrate that CCH needs only about half of the rooms for which they are licensed. However, as will be shown, patients in Lee County have limited access to surgical services. The need calculation does not consider the following:

- CCH does not have all of its ORs set up and staffed;
- CCH surgeons on staff have declined; and
- CCH has a monopoly on surgery in the county, which has stifled competition.

As a result, there are large and increasing numbers of patients leaving the county for surgery. In addition, the quality of surgery available in the county has suffered and access to care is unreasonable and inequitable. With a perpetual surplus of ORs in the SMFP, there is no opportunity to address the access issues faced by Lee County residents.

Under the SMFP methodology, there will not be an opportunity to introduce a competing provider or address outmigration in Lee County for the foreseeable future. Additionally, there will continue to be a lack of competition and none of positive impact of competition on quality. Because access to care is limited, surgical volume has declined despite population growth and aging. With the approval of the current petition, PSC seeks to remedy these issues.

Lack of access to outpatient surgical care for Lee County residents is illustrated by:

- Lee County population is growing and aging, which typically drives an increase in surgical utilization.
- Yet, contrary to demographic trends, Lee County resident surgical utilization is declining.
- Lee County has a high poverty rate and high level of uninsured residents for whom local access to care is critical.
- However, a large and growing percentage of Lee County residents are having to leave the area for care.

These concerning trends are the result of limited local access to care, which has an adverse effect on providers and consumers in the county. In addition, having only one, hospital-based, provider within the county does not allow for choice of a less costly alternative such as an ambulatory surgery center (“ASC”). Furthermore, having only one provider does not have the beneficial aspects of competition on care provided to patients: benefits such as increased quality of care due

to competition within the service area.

PSC is respectfully requesting a petition to recognize a need for two ORs in the 2022 SMFP so that an ASC with two ORs could be developed to increase access and choice of care for residents of Lee County. In addition to increasing access to care, patients will be provided quality outpatient surgical care at much lower rates in an ASC setting as compared to a hospital setting. This amounts to more cost-effective care, which is an option that is currently unavailable to Lee County residents locally. Without the proposed adjustment, there will be no OR need for the foreseeable future and both consumers and providers will continue to experience the adverse effect of limited local access to care without a less costly, high quality option. Physicians and community members strongly support the proposed adjustment to provide for greater local access, a less costly, high-quality alternative provider, and a choice for patients and providers. Please see **Attachment A** for letters of support for the proposed adjustment.

ANALYSIS IN SUPPORT OF THE PROPOSED ADJUSTMENT

Lee County Population is Growing and Aging

An overview of Lee County’s demographic trends must be established in order to understand the lack of access to, and the need for, an additional outpatient OR provider within the county. First, as illustrated in **Exhibit 2**, below, the overall population in Lee County has been growing more quickly on average than the state as a whole from 2016 through 2019. During this period, Lee County grew at a compounded annual growth rate (“CAGR”) of 1.4 percent, while North Carolina’s population increased at only a 1.1 percent CAGR. Additionally, the aging population (ages 65 and older) in Lee County is growing much faster than any other age cohort in the county. Historically, the aging population tends to use healthcare resources at a higher rate than any other age cohort. An aging and increasing population typically results in increasing utilization of healthcare services such as outpatient surgery.

**Exhibit 2
4 Year Population Trend for Lee County and North Carolina**

2016-2019 Lee County Population Growth					
Year	Age 0-17	Age 18-44	Age 45-64	Age 65+	Total
2016	14,888	19,814	15,178	9,301	59,181
2017	14,934	20,022	15,277	9,577	59,810
2018	15,000	20,537	15,378	9,963	60,878
2019	15,116	20,882	15,410	10,282	61,690
Lee County CAGR	0.5%	1.8%	0.5%	3.4%	1.4%
North Carolina CAGR	0.0%	1.0%	0.7%	3.6%	1.1%

Source: North Carolina Office of State Budget and Management

Lee County has High Rates of Poverty and Uninsured Residents

Further emphasizing the need for more cost-effective outpatient surgical options in Lee County is the poverty level within the county. As shown in **Exhibit 3**, according to the U.S. Census Bureau, Lee County has a higher rate of poverty than both the National rate and the North Carolina rate. In addition, Lee County has a lower median household income and per capita income than the North Carolina and National levels. Finally, Lee County has a higher rate of uninsured residents than North Carolina and the U.S. Given the rural nature of Lee County, and the large percent of residents living in poverty and without health insurance, increasing local access to outpatient surgical services at a lower cost is imperative. Currently, local access is limited to just one local hospital.

Exhibit 3
US Census Bureau 2015-2019 Income & Poverty

	National	North Carolina	Lee County
Median household income	\$ 62,843	\$ 54,602	\$ 49,994
Per capita income in past 12 months	\$ 34,103	\$ 30,783	\$ 24,842
Persons in poverty, percent	10.5%	13.6%	14.2%
Persons without health insurance (under age 65)	9.5%	13.4%	15.9%

Source: US Census Bureau, Quickfacts

As previously stated, CCH, a hospital, is the only provider of outpatient surgical services in the county. If this single provider is not financially accessible, then patients have no choice but to leave the area for surgical care. In 2018, 2019, and 2020, CCH reported providing just one charity care ambulatory surgery case each year.¹ With 14.2 percent of residents living in poverty and 15.9 percent uninsured, it is clear that local access to care is limited for Lee County residents. Insured patients and their payors are also paying higher hospital rates for their care. This has a direct impact on consumers. Patients with high deductible health insurance plans are paying larger amounts for surgery for hospital-based care.

Without a need adjustment, the current status of surgery in Lee County is unlikely to change with severely limited access to care. An adjustment to the need determination would allow for the establishment of a freestanding, non-hospital-based ASC in Lee County that will provide residents with a lower cost option for outpatient surgical services.

Surgical Utilization by Lee County Residents is Declining

As discussed above, Lee County is experiencing growth in its overall population and aging population. With this growth and aging in population, there will also be an expectation of growth in the utilization of outpatient surgical services. However, the opposite trend has been experienced. Lee County residents' outpatient surgical volume has declined by 4.9 percent from 2016 to 2019 or a CAGR of 1.7 percent as shown in **Exhibit 4**, below.² By contrast, outpatient

¹ See CCH 2021, 2020, and 2019 Licensure Renewal Applications Part E.

² PSC focused on data through 2019 in order to avoid conflating the effects of the COVID-19 Pandemic.

surgical cases in North Carolina have exceeded population growth rates. Such a counter-indicated trend for Lee County is indicative of limited access to local surgical care.

Exhibit 4
Trend in Lee County Resident Outpatient Surgical Volume

Year	Lee County	North Carolina
2016	4,405	657,644
2017	4,354	666,204
2018	4,309	665,492
2019	4,187	681,914
% Change in Surgery	-4.9%	3.7%
Surgery CAGR%	-1.7%	1.2%
Population CAGR%	1.3%	1.1%

Source: NC DHSR 2018-2020 Patient Origin Reports, 2018-2021 SMFPs

The declining outpatient surgical volume for Lee County residents is reflective of an actual decline in surgical use rates for county residents as shown in **Exhibit 5**. Between FY2016 and FY 2019, outpatient surgery use rates declined by 8.81 percent while use rates per 65 and older residents declined by 14 percent. Such significant declines in use rates raise substantial concerns about access to care within Lee County.

Exhibit 5
Trend in Lee County Outpatient Surgery Use Rates

	2016	2017	2018	2019	% Change
Lee County Resident Surgical Volume	4,405	4,354	4,309	4,187	-4.95%
Lee County Population	59,181	59,810	60,878	61,690	4.24%
Use Rate per 1,000 Residents	74.43	72.80	70.78	67.87	-8.81%
Lee County 65+ Population	9,301	9,577	9,963	10,282	10.55%
Use Rate per 1,000 65+ Residents	473.60	454.63	432.50	407.22	-14.02%

Source: NC DHSR 2018-2020 Patient Origin Reports

It is clear that Lee County residents are accessing outpatient surgery at declining rates counter to expected and prevailing trends.

Historical Utilization of the Sole Lee County Hospital is Limited

As established, Lee County has a sole provider of outpatient and inpatient surgical services, Central Carolina Hospital. As such, Lee County residents have only had one choice for a surgery provider unless they have chosen to leave the county. OR capacity in Lee County has remained constant over the last 4 years, however outpatient volume and surgical hours has declined; see **Exhibit 6**, below. Despite population growth and aging, the outpatient surgical utilization of the existing hospital has steeply declined. The surgical hours at CCH have declined even more than the surgical cases, suggesting that the complexity of cases is also decreasing, which would in turn suggest that more complex cases are having to leave the area.

Exhibit 6
Lee County Summary of OR Utilization

	FY2016	FY2017	FY2018	FY2019	CAGR
Central Carolina Hospital (Lee)					
OR Inventory	6	6	6	6	
Outpatient Cases	3,053	3,161	3,020	2,579	-5.5%
Surgical Hours	4,518	3,741	3,931	3,697	-6.5%

Source: 2018-2021 SMFP

The SMFP only counts the number of existing and approved ORs and does not account for whether an OR is set up and staffed. The SMFP recognizes all ORs in its inventory and capacity whether the ORs are actually in use or not. In his letter of support, Dr. Paul Heimbecker, MD confirms that all of the ORs at CCH are **not** set up and staffed, and he had to seek privileges at a distant hospital to perform surgeries:

This year I had to get surgical privileges at a hospital 30 miles away just to have more opportunity to do surgeries. The limitations for surgical times this past year have been primarily due to an unstaffed OR. There were service lines like dentistry and podiatry that were asked not to bring their surgeries to CCH.

- Paul Heimbecker, MD

Not only are the ORs at CCH not fully set up and staffed, but some physicians are also being asked to not bring their surgical cases to the hospital. In some instances, like Dr. Heimbecker, physicians must travel 30 miles one way in order to have surgical time.

Furthermore, physician staffing at CCH has dropped off tremendously over the last few years. From January 2018 to year to date (“YTD”) 2021, the orthopedic surgeon full-time employees (“FTEs”) has gone from 1 to 0. The OB/GYN staffing is even more dire. From January 2018 to YTD 2021, the OB/GYN staffing at CCH has gone from 6 to a single physician under a locum tenens model. CCH lacks sufficiently set up and staffed ORs and lacks sufficient physician staffing to support the patient population of Lee County. As noted in a letter of support, staffing at CCH has steadily declined:

At that time there were only three OR nurses and two full time surgical technicians. The OR was only running two rooms a day. Medical staff declined. The ENT surgeon, three OBGYNS, and all Pediatric Dentists left. The two urologists had retired but they were in the process of recruiting a group out of Raleigh. Locum OBGYNS now cover the Labor & Delivery Department along with mostly locum nurses. Orthopedic services are limited. The community is aware of these issues and they are not fond of the inconsistency of care.

- Susette G. Taylor, CRNA

An adjustment to the SMFP need determination would more accurately reflect the actual limited access to OR capacity and surgical services local in Lee County and allow an applicant to apply to expand access to care for Lee County residents.

Lee County Residents are Leaving the Area to Receive Outpatient Surgery (Outmigration)

The North Carolina Department of Health and Human Services (“NCDHHS”) Patient Origin Reports provide information that shows where the residents of a county are going for outpatient surgery. **Exhibit 7** summarizes the trend for Lee County residents receiving outpatient surgery from fiscal year (“FY”) 2016 through FY2019. These data show that the amount of Lee County residents receiving outpatient surgery within Lee County has declined 28.6 percent over this period. By contrast, the Lee County residents leaving the county (“outmigrating”) for outpatient care has steadily increased. By 2019, over 68 percent of Lee County residents were leaving the county for outpatient surgical services. Again, overall, the rate of outpatient surgical utilization for county residents has significantly declined. These data further confirm a lack of locally accessible outpatient surgery.

Exhibit 7
Outmigration of Lee County Residents for Outpatient Surgical Services

Location of Care	2016	2017	2018	2019	% Change
Within Lee County	1,869	1,968	1,752	1,334	-28.6%
Outside of Lee County	2,536	2,386	2,557	2,853	12.5%
Total	4,405	4,354	4,309	4,187	-4.9%
% Outmigration	57.6%	54.8%	59.3%	68.1%	

Source: NC DHSR 2018-2020 Patient Origin Reports

The increasing outmigration trend raises the question, where are Lee County patients going to receive outpatient surgical services? **Exhibit 8**, below, depicts where Lee County went to receive outpatient surgical services by location for 2019. While some Lee County patients travel to UNC (Orange County), Duke (Durham County), Rex (Wake County), and WakeMed (Wake County), the majority of patients are traveling into Moore County (FirstHealth, PSC, and The Eye Surgery Center of the Carolinas) to receive outpatient surgical services. Overall, 31.8 percent of Lee County patients traveled to Moore County, which is almost identical to the 31.9 percent of patients staying within Lee County. In other words, as many Lee County patients travel to Moore County for care as those who stay in Lee County for care. With this petition, PSC seeks to reverse the trend of outmigration by creating an adjustment to need to allow for a second outpatient surgical provider in Lee County.

Exhibit 8
Facility Destination of Lee County Patients - 2019

Facility Type	Facility	Volume	Percentage
HOSP	Central Carolina Hospital	1,334	31.9%
HOSP	University of North Carolina Hospitals	604	14.4%
HOSP	FirstHealth Moore Regional Hospital	528	12.6%
ASC	Surgery Center of Pinehurst (PSC)	475	11.3%
ASC	The Eye Surgery Center of the Carolinas	331	7.9%
HOSP	Duke University Hospital	123	2.9%
HOSP	Rex Hospital	79	1.9%
ASC	Rex Surgery Center of Cary	67	1.6%
HOSP	Duke Raleigh Hospital	65	1.6%
ASC	Blue Ridge Surgery Center	65	1.6%
HOSP	WakeMed Cary Hospital	64	1.5%
HOSP	WakeMed	52	1.2%
HOSP	Chatham Hospital	50	1.2%
	All Other Facilities	350	8.4%
	Total	4,187	100.0%

Source: NC DHSR Patient Origin Report 2019

While the SMFP accounts for the declining outpatient volume in Lee County, it does not account for the outmigration of Lee County residents to surrounding counties for outpatient surgical services that support the need for increased access to care within Lee County. In addition, the SMFP need methodology does not account for the fact that the overall surgical case volume for Lee County residents is declining, which is consistent with a declining level of access to care.

The letters of support for this petition highlight the high levels of patients leaving Lee County in order to receive outpatient surgical services due to lack of access locally. One letter of support captures this trend:

All known outpatient surgical procedures to relatives have been outside of Lee County due to the limited options for this area.

*-Tom Aguilar, Production Manager
Caterpillar, Inc.*

As noted in another letter of support, patients are choosing to go to providers other than CCH for their healthcare need:

I am not only a long time resident of Lee County but I am a Registered Nurse who worked at CCH for 27 years. I am saddened by the state of affairs of our current healthcare options. I no longer work for CCH and I most certainly would not choose CCH for my health care needs.

*Cathi Von Canon, RN
Lee County Resident*

Patient dissatisfaction and staffing turnover are also cited as reasons for lack of local access to care:

Having served on the local Hospital Board a number of years back, I have followed the patients' comments and valuation of health care extended to them. Today, I continue to hear negative remarks in regard to emergency room wait time, unsuccessful surgery, loss of staff (both doctors and nurses), under existing ownership policy. This is unacceptable in a growth city, where we need good and improved health care. I can cite many residents refusing care in this facility and going to other hospitals. This needs to be addressed.

*George R. Perkins, Jr.
CEO, Perkins Investments, LLC*

Patients traveling to distant locations in order to receive faster surgery scheduling is noted in a physician letter of support:

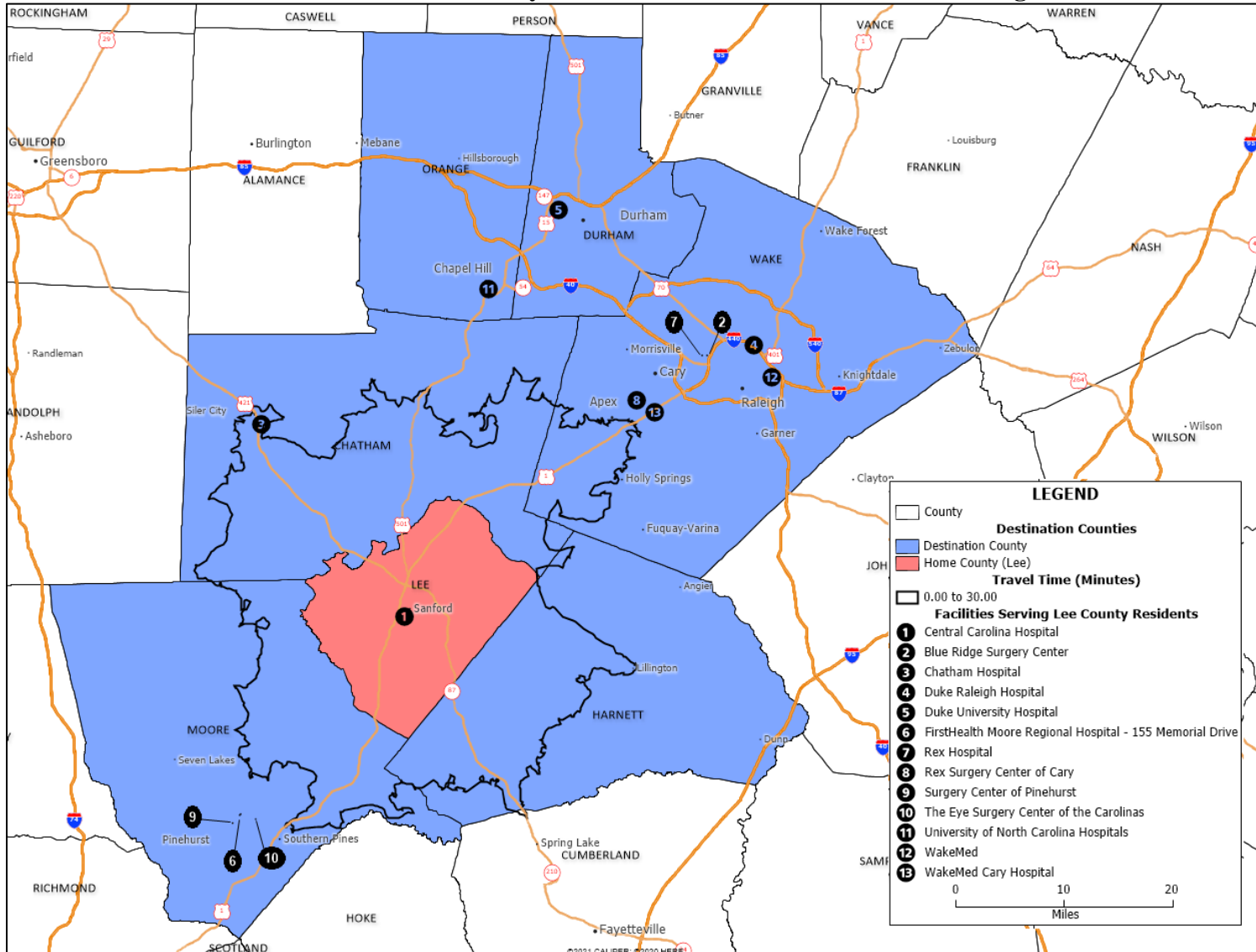
My patients have personally experienced difficulties due to the limited availability of outpatient surgery in Lee County. We have lost patients to Raleigh/Durham as patients seem to get scheduled for surgery faster there.

*Cynthia Z. Africk, MD, FAANS, FACS
Neurosurgeon, FirstHealth/UNC Department of Neurosurgery*

Travel Access to Surgical Services

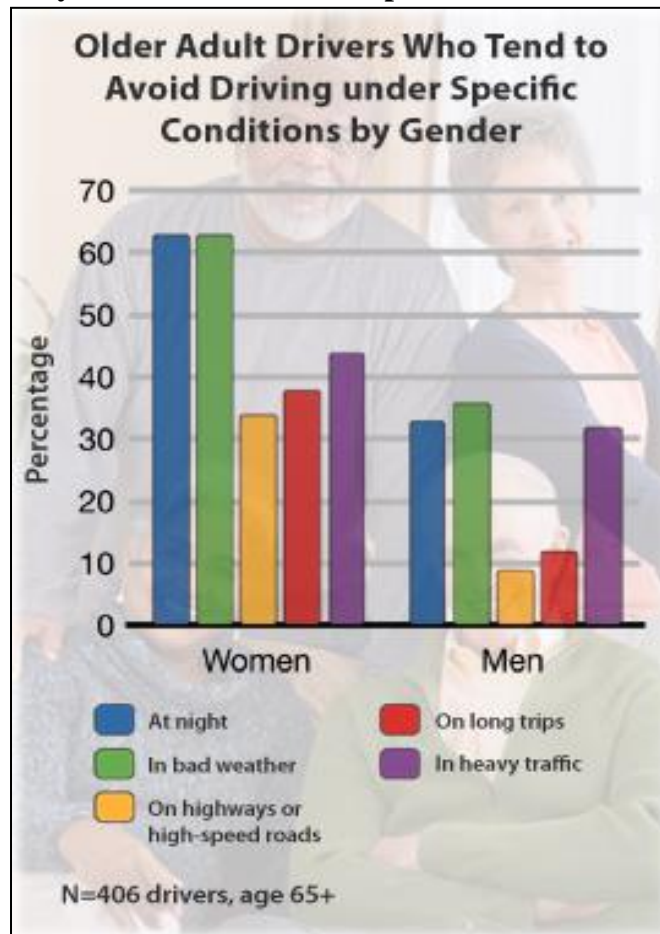
Exhibit 9, below, is a map with a 30-minute drivetime contour around Stanford, Lee County's population center. The map also shows the locations of provider where 91 percent of Lee County patients travel in order to receive outpatient surgical services. Aside from CCH, all the other locations are at least a 30-minute drive from the center of Sanford, Lee County, North Carolina. Lee County residents (31.9%) traveling to Moore County have at least a 30-minute drive one way adding to a long surgery day. Another 28 percent of patients traveling to Raleigh and Durham are also traveling well more than 30 minutes one way for surgery. These patients likely include those traveling for more specialized procedures at the tertiary providers in these areas. Despite the long drivetime of 30 minutes or more, increasing numbers of patients are travelling to receive the care they need. As the total surgical case volume and surgical use rates decline, it is also reasonable to assume that an increasing number of patients are not getting the surgical care they need.

Exhibit 9 Destination of Lee County Residents with 30-Minute Drivetime Ring



Such travel is a burden for patients and their caregivers, especially transportation post-surgery. Additionally, the elderly population does not like to travel at night or in bad weather conditions. **Exhibit 10**, below, reveals the results of a driving study published by the Centers for Disease Control and Preventions regarding elderly US citizens and their reticence to drive in various conditions. This study reveals that most elderly drivers limit their driving at night and bad weather. Additionally, a significant number of the elderly avoid driving altogether due to long trips, heavy traffic, or highways/high-speed roads. Such driving concerns impact where (and if) a patient decides to receive care.

Exhibit 10
Elderly Drivers' Aversion to Specific Road Conditions



Source: <http://www.cdc.gov/Features/dsOlderDrivers/>

Interestingly, the article provides safety tips to elderly patients who have to drive. One tip recommends “*considering potential alternatives to driving, such as riding with a friend or using public transit that you could use to get around.*” Public transit is not necessarily a feasible alternative mode of transportation when living in a rural area such as Lee County. Having readily available outpatient surgical services locally will be beneficial for elderly patients within Lee County as the elderly population is growing in the county.

Such distant travel for care also places the heaviest burden on low-income individuals and those living in poverty. Such patients are more likely to face limited options for travel such as having only one family car (if any). When a family member must take an entire day off from work to transport a patient to and from a distant surgical provider, the loss of wages and/or time off is similarly a larger burden to low-income residents. Thus, traveling 30 minutes (60 minutes round trip) for outpatient surgery for some Lee County residents may not be feasible at all.

Pinehurst and FirstHealth Are Increasingly Serving Lee County

As previously discussed, fewer and fewer Lee County residents are receiving outpatient surgical services from CCH and are instead seeking services from a number of other distant facilities, including FirstHealth and PSC. Data from the NCDHHS Patient Origin report show a drastic decline in Lee County volume for CCH accompanied by a drastic increase in Lee County volume for FirstHealth and PSC; see **Exhibit 11**, below. This data further validates the need for enhanced access to outpatient surgical services in Lee County. Patients do not feel they have access to quality outpatient surgical services and physicians are unable to schedule surgery time at CCH. Moreover, surgical specialties are increasingly limited. As will be shown, CCH’s charity care track record also limits patients access to local surgical care.

**Exhibit 11
Trend in Lee County Patient Volume**

Facility	2017	2018	2019	% Change	CAGR
FirstHealth Moore Regional Hospital	352	490	528	50.0%	22.5%
Surgery Center of Pinehurst	359	359	475	32.3%	15.0%
Central Carolina Hospital	1,968	1,752	1,334	-32.2%	-17.7%

Source: NCDHHS Patient Origin Reports

Reversing Outmigration Would Support 2 ORs

Using data from the NC DHSR 2020 Patient Origin Report (FY 2019) and the OR need methodology from the Draft 2022 SMFP, reversing even just half of the outmigration from Lee County would support 2 ORs based on incremental cases alone as shown in **Exhibit 12**. By increasing local access to outpatient surgery, the volume of Lee County patients receiving surgery should increase at the rate of population growth, at minimum, consistent with the statewide trend shown **Exhibit 4**, above. This would result in a projection of 4,452 outpatient surgery cases in 2024, the planning horizon for the 2022 SMFP. If outmigration is cut in half between 2019 to 2025 (from 68.1 percent to 34.1 percent) there would be 2,935 outpatient surgical cases staying in Lee County with 1,601 of those cases being incremental cases for the local market.

An applicant for the proposed need adjustment would have to be an ASC facility; therefore, it will be assigned to Group 6 according to the SMFP. Multiplying the incremental cases by the case weight (1,601 cases X 1.16) results in an OR hours needed of 1,857. Lastly, dividing the hours needed by the Group 6 standard hours of 1,312 results in a need of 1.42 ORs. In the SMFP under Ch. 6, Step 6 of the OR Need Methodology, any deficit resulting in 0.30 or higher is rounded to the next whole number. Therefore, an OR need of 1.42 would be rounded to a

need of 2.0 ORs for Lee County to address just half of the current outmigration level. Using the methodology from the SMFP supports two additional ORs in Lee County.

**Exhibit 12
Projected OR Need**

	2019	2024
Total Lee County Resident Cases ³	4,187	4,452
% Outmigration from Lee County	68.1%	34.1%
% of Cases Staying in Lee County	31.9%	65.9%
Cases Staying in Lee County	1,334	2,935
Incremental Cases Staying in Lee County		1,601
Case Weight (Group 6)		1.16
Hours Needed		1,857
Standard Hours (Group 6)		1,312
ORs Needed		1.42

Source: NC DHSR 2020 Patient Origin Report and 2021 SMFP

Importantly, by reversing outmigration, any new outpatient surgical provider in Lee County could readily fill 2 ORs without taking cases from CCH. While CCH certainly has the capacity to serve these cases if they stayed in the county, CCH has demonstrated that it is unable to stem the increased level of outmigration from the county. Nor has CCH been able to ensure that Lee County residents have adequate access to care as demonstrated by declining outpatient surgery use rate and loss of physicians.

High Demand for Facilities that Provide More Cost-Effective Care

Patients who have outpatient surgery in an ASC pay significantly lower out-of-pocket costs than patients that receive outpatient surgery in a hospital setting. In fact, according to CMS reimbursement rates, it costs Medicare just 53 percent of the amount paid to Hospital Outpatient Departments ("HOPDs") for the same procedure performed in an ASC setting.⁴ This amounts to real savings for the Medicare-covered patient due to lower copays to cover out-of-pocket costs in an ASC setting as opposed to a hospital setting. In a detailed study entitled *Medicare Outpatient Differentials Across Settings of Care*, routine procedures such as screening colonoscopy may be as much as \$400 higher in an HOPD compared to an ASC setting. **See Attachment B.** This study more fully expands the cost differential analysis to the episode of care surrounding the procedure such as pre-op and post-op care. Overall, the patients and payors in Lee County would benefit from an alternative ASC setting in their local community, which can only be achieved if a need adjustment is recognized in the SMFP.

³ FY2019 Lee County resident surgical cases projected to increase by 1.2% CAGR population growth to the 2024 planning horizon.

⁴<https://www.ascassociation.org/advancingsurgicalcare/reducinghealthcarecosts/paymentdisparitiesbetweenascsandhopds>

Efforts to Coordinate Care

Collaborative efforts between two or more healthcare organizations can lead to cost-saving alternatives for patients that are served by those organizations. PSC has such a relationship in place with FirstHealth Moore Regional Hospital (“FirstHealth”) to ensure patients receive surgical access in the most cost-effective setting closest to home. Physicians from FirstHealth are highly supportive of the proposed need adjustment and the establishment of a second outpatient surgery option in Lee County to increase local access to care. Please see **Attachment A** for letters of support from Lee County residents and community stakeholders, as well as FirstHealth physicians.

CONSISTENCY WITH STATE HEALTH PLANNING PRINCIPALS

PSC's request for the adjusted need determination to two additional ORs is consistent with the following principals governing the development of the North Carolina Medical Facilities Plan:

Safety and Quality:

An additional two ORs in Lee County would improve upon the safety and quality of care available locally in Lee County. One of the beneficial aspects of competition is to ensure the highest level of quality of care, including patient satisfaction. Without the benefit of competition and the status quo of a monopoly situation in Lee County, patients will continue to leave the area when services and specialties are not available or accessible and when safety and quality are poor, as demonstrated in numerous letters of support for this petition.

The additional ORs in an ASC setting in Lee County will allow patients to obtain a larger range of specialty outpatient surgical care closer to home. ASCs are well-recognized for providing high quality, safe patient care at lower cost to patients and payors. In this instance, safety and quality will be improved while also allowing for expanded access to care and reducing costs for Lee County residents in their own community. Without the proposed adjusted need determination, there will be no opportunity to introduce competition and the associated beneficial impact on safety and quality in Lee County for the foreseeable future.

Access Basic Principle:

As discussed above, there are significant indications of lack of access to outpatient surgery services for Lee County residents. Declining outpatient surgical volume despite population growth and aging in Lee County is indicative of access issues. Furthermore, travel to distant outpatient surgical providers is a burden on patients and their families, especially the elderly and low-income populations. Finally, the existing local hospital does not have a track record of ensuring financial access to outpatient surgery providing care to just 1 charity care outpatient surgery patient in FY 2018, FY 2019, and FY 2020.

Access to quality, affordable outpatient surgical services for Lee County residents will be promoted by the introduction of a competing surgical provider. Given the perpetual surplus of ORs in Lee County, it is unlikely that there would be a need recognized for many years in the absence of the proposed adjusted need determination. An adjusted need determination for 2 ORs

would allow for a much-needed ASC to be developed in Lee County.

The additional ORs in an ASC setting would reduce outmigration for care and provide Lee County residents a more affordable option closer to home and enhance competition in the area. Reducing travel for care will provide significant benefit to patients and their families or caregivers, who often have to provide transportation not only for the surgery procedure itself but also for pre- and post-op visits. Traveling more than an hour to an hour roundtrip for surgery and follow-up can be a hardship to patients, particularly those most vulnerable populations such as the elderly or low-income residents of Lee County. Providing a choice of a lower cost surgical provider in Lee County will improve choice of facility setting benefiting consumers and both government and private payors.

Additionally, Lee County physicians will be afforded an option of where they can perform surgery. Physicians are currently experiencing difficulty scheduling surgery time at CCH or are traveling long distances in order to schedule time at alternative locations. With the addition of a freestanding ASC with two ORs, physicians will be able to schedule their patients for surgery in a cost-effective setting closer to home.

Value Basic Principle:

The proposed adjusted need determination for additional ORs will also promote value. As previously discussed, costs and charges are much lower in a freestanding, non-hospital-based ASC setting than a HOPD. With outmigration for outpatient surgical procedures increasing for Lee County residents, patients should be provided the opportunity to receive affordable care closer to home in an ASC setting. By adding an adjusted need determination for two ORs in Lee County in the 2022 SMFP, an opportunity would be created for the development of a new ASC.

CONCLUSION

The SMFP OR need methodology does not recognize the unique access issues for outpatient surgical services faced by Lee County residents. The ORs counted in the need methodology are not fully set up and staffed, and physicians have documented lack of scheduled OR time at the sole surgical provider in Lee County. Physician staffing at the local hospital has diminished and multiple specialties are either not available or severely limited. Quality of care issues have also been documented in letters of support.

As a result, residents of Lee County are increasingly leaving the area and traveling long distances for outpatient surgery, which is a burden for patients and their caregivers. As long as patients must out-migrate for accessible, high-quality care, there will be no need generated in the SMFP under the current facility-based need methodology for the foreseeable future. The lack of local access creates the largest burden on the elderly and low-income individuals who typically face the most difficulty in traveling for care. Without a need adjustment, there will never be any opportunity to increase access to surgical services nor will there ever be an alternative to the one hospital in the market. While a basic tenet of CON is to prevent duplication of services, the benefits of competition are also recognized within the CON Statute. The introduction of competition in Lee

County will have the benefits of increasing local access, reducing cost, and ensuring quality of care. Without an adjusted need determination, there will not be an opportunity to provide the introduction of competition and its benefits for residents of Lee County for the foreseeable future.

Thank you for your consideration.

Attachment A

Letters of Support

*Susette G. Taylor. CRNA
2648 Buckingham Dr
Sanford. NC 27330
910-280-3921
Miley29933@gmail.com*

07/27/2021

North Carolina State Health Coordinating Council
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for an adjusted need determination for 2 additional operating rooms in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan*.

To Whom It May Concern:

My name is Susette Taylor and I am a Sanford, NC resident and a former employee of Apollo MD. The Anesthesia service that provided anesthesia care to Central Carolina Hospital. I am writing this letter to support the petition submitted by Pinehurst Surgical Clinic (“PSC”) for an adjusted need determination for 2 additional operating rooms (“OR”) in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan* (“SMFP”).

Historically there has been one hospital, Central Carolina Hospital, with 1 inpatient OR and 6 shared ORs in Lee County. Given its rural nature, the SMFP does not fully capture the need for additional ambulatory surgery services in Lee County. Over a four-year period, Lee County has experienced extensive outmigration for ambulatory surgery services. From 2016 to 2019, outpatient surgical volume at Central Carolina Hospital has declined, while outmigration from Lee County for outpatient surgical services has steadily increased. In 2019 alone, Lee County experienced **an outmigration of 49.8 percent for ambulatory surgery services**.

PSC believes it is important for Lee County patients to have access to surgery service close to home. In 2020 PSC had over 2,000 outpatient referrals from Lee County and these patients were primarily served in Moore County facilities. This outmigration places a burden on patients and their families. My patients have personally experienced difficulties due to the limited availability of outpatient surgery in Lee County.

As a former CRNA at CCH, I have firsthand knowledge of the migration of patient’s and medical staff out of the Lee County area. Nursing staff and the medical staff have reduced itself to a bare

*Susette G. Taylor. CRNA
2648 Buckingham Dr
Sanford. NC 27330
910-280-3921
Miley29933@gmail.com*

minimum. I left CCH in March. At that time there were only three OR nurses and two full time surgical technicians. The OR was only running two rooms a day. Medical staff declined. The ENT surgeon, three OB GYNs, and all Pediatric Dentists left. The two urologists had retired but they were in the process of recruiting a group out of Raleigh. Locum OB GYNs now cover the Labor & Delivery Department along with mostly locum nurses. Orthopedic services are also limited. The community is aware of these issues and they are not fond of the inconsistency of care.

The employees that I worked with in the OR discussed the hopes that the hospital would be purchased again, hopefully by First Health and Pinehurst Surgical. The problem with this is the condition of the physical plant. I have experienced on multiple occasions it raining through the roof in the OR. It also rains in central sterile. Instruments have had to be sent out for reserialization on multiple occasions. Repeated attempts were made for repair, but none were successful while I was employed there. I have been present when sewage from the upstairs room poured through the roof of the OR Doctor's lounge on multiple occasions. Sewage was also present in the call room shower bathroom and bathroom sink on frequent occasions.

I commute to Myrtle Beach, SC now for employment but my husband and I do plan to retire in Sanford. It would give me great peace of mind to know that I had a facility in this town where we could receive quality care.

Due to the limited options for surgical care in Lee County, large numbers of patients are leaving Lee County for their surgery. This out-migration is not captured in the SMFP, and as a result, there is no need recognized in the 2022 Draft SFMP that would allow for Lee County residents to have a choice in surgical care within their home county. The amount of patients outmigrating from Lee County would support a need for, at minimum, one or more ORs.

Lee County residents would significantly benefit from access to a second surgical option within the county. I fully support the requested petition to recognize a need for 2 ORs in the 2022 SMFP. An ambulatory surgery center with 2 ORs could be developed to increase access and choice of care for residents of Lee County. In addition, patients are provided quality outpatient surgical care at much lower rates in an ASC setting than they are in a hospital OR. This amounts to more cost-effective care being provided in an ASC setting, which is an option unavailable to Lee County residents locally today.

Sincerely,

Susette G. Taylor
Susette G. Taylor
CRNA

Cynthia Z. Africk, MD, FAANS, FACS
FirstHealth/UNC Neurosurgery
Clinical Associate Professor
Department of Neurosurgery
10 Aviemore Drive
Pinehurst, NC, 28374

June 29, 2021

North Carolina State Health Coordinating Council
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for an adjusted need determination for 2 additional operating room in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan*.

To Whom It May Concern:

My name is Cynthia Africk and I am a resident of Moore County. I am writing this letter to support the petition submitted by Pinehurst Surgical Clinic ("PSC") for an adjusted need determination for 2 additional operating rooms ("OR") in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan* ("SMFP").

Historically there has been one hospital, Central Carolina Hospital, with 1 inpatient OR and 6 shared ORs in Lee County. Given its rural nature, the SMFP does not fully capture the need for additional ambulatory surgery services in Lee County. Over a four-year period, Lee County has experienced extensive outmigration for ambulatory surgery services. From 2016 to 2019, outpatient surgical volume at Central Carolina Hospital has declined, while outmigration from Lee County for outpatient surgical services has steadily increased. In 2019 alone, Lee County experienced an outmigration of 49.8 percent for ambulatory surgery services.

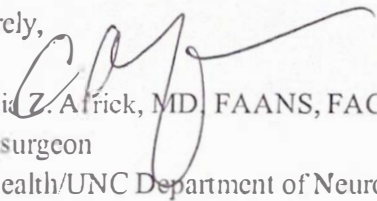
PSC believes it is important for Lee County patients to have access to surgery service close to home. In 2020 PSC had over 2,000 outpatient referrals from Lee County and these patients were primarily served in Moore County facilities. This outmigration places a burden on patients and their families. My patients have personally experienced difficulties due to the limited availability

of outpatient surgery in Lee County. We have lost patients to Raleigh/Durham as patients seem to get scheduled for surgery faster there.

Due to the limited options for surgical care in Lee County, large numbers of patients are leaving Lee County for their surgery. This out-migration is not captured in the SMFP, and as a result, there is no need recognized in the 2022 Draft SFMP that would allow for Lee County residents to have a choice in surgical care within their home county. The amount of patients outmigrating from Lee County would support a need for, at minimum, one or more ORs.

Lee County residents would significantly benefit from access to a second surgical option within the county. I fully support the requested petition to recognize a need for 2 ORs in the 2022 SMFP. An ambulatory surgery center with 2 ORs could be developed to increase access and choice of care for residents of Lee County. In addition, patients are provided quality outpatient surgical care at much lower rates in an ASC setting than they are in a hospital OR. This amounts to more cost-effective care being provided in an ASC setting, which is an option unavailable to Lee County residents locally today.

Sincerely,



Cynthia Z. Africk, MD, FAANS, FACS
Neurosurgeon
FirstHealth/UNC Department of Neurosurgery

June 8, 2021

North Carolina State Health Coordinating Council
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for an adjusted need determination for 2 additional operating room in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan*.

To Whom It May Concern:

My name is Henny Liwan, M.D. and I am an Ob/Gyn Physician practicing at NCCRM currently. I am writing this letter to support the petition submitted by Pinehurst Surgical Clinic ("PSC") for an adjusted need determination for 2 additional operating rooms ("OR") in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan* ("SMFP").

Historically there has been one hospital, Central Carolina Hospital, with 1 inpatient OR and 6 shared ORs in Lee County. Given its rural nature, the SMFP does not fully capture the need for additional ambulatory surgery services in Lee County. Over a four-year period, Lee County has experienced extensive outmigration for ambulatory surgery services. From 2016 to 2019, outpatient surgical volume at Central Carolina Hospital has declined, while outmigration from Lee County for outpatient surgical services has steadily increased. In 2019 alone, Lee County experienced **an outmigration of 49.8 percent for ambulatory surgery services.**

PSC believes it is important for Lee County patients to have access to surgery service close to home. In 2020 PSC had over 2,000 outpatient referrals from Lee County and these patients were primarily served in Moore County facilities. This outmigration places a burden on patients and their families.

Due to the limited options for surgical care in Lee County, large numbers of patients are leaving Lee County for their surgery. This out-migration is not captured in the SMFP, and as a result, there is no need recognized in the 2022 Draft SFMP that would allow for Lee County residents to have a choice in surgical care within their home county. The amount of patients outmigrating from Lee County would support a need for, at minimum, one or more ORs.

Lee County patients would significantly benefit from access to a second surgical option

within the county. I fully support the requested petition to recognize a need for 2 ORs in the 2022 SMFP. An ambulatory surgery center with 2 ORs could be developed to increase access and choice of care for residents of Lee County. In addition, patients are provided quality outpatient surgical care at much lower rates in an ASC setting than they are in a hospital OR. This amounts to more cost-effective care being provided in an ASC setting, which is an option unavailable to Lee County residents locally today.

Sincerely,

A handwritten signature in black ink, appearing to read "Henny Liwan", written over a horizontal line.

Henny Liwan, M.D.

5/25/21

North Carolina State Health Coordinating Council
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for an adjusted need determination for 2 additional operating room in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan*.

To Whom It May Concern:

My name is Mary Florit and I am a resident of Lee County. I am writing this letter to support the petition submitted by Pinehurst Surgical Clinic ("PSC") for an adjusted need determination for 2 additional operating rooms ("OR") in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan* ("SMFP").

Historically there has been one hospital, Central Carolina Hospital, with 1 inpatient OR and 6 shared ORs in Lee County. Given its rural nature, the SMFP does not fully capture the need for additional ambulatory surgery services in Lee County. Over a four-year period, Lee County has experienced extensive outmigration for ambulatory surgery services. From 2016 to 2019, outpatient surgical volume at Central Carolina Hospital has declined, while outmigration from Lee County for outpatient surgical services has steadily increased. In 2019 alone, Lee County experienced an outmigration of 49.8 percent for ambulatory surgery services.

PSC believes it is important for Lee County patients to have access to surgery service close to home. In 2020 PSC had over 2,000 outpatient referrals from Lee County and these patients were primarily served in Moore County facilities. This outmigration places a burden on patients and their families. My daughter recently had a kidney stone. When seen at Central Carolina Hospital, she was told not to return if she didn't pass the stone, as they didn't have a physician who could treat her. She had to leave Lee County for surgical treatment.

Due to the limited options for surgical care in Lee County, large numbers of patients are leaving Lee County for their surgery. This out-migration is not captured in the SMFP, and as a result, there is no need recognized in the 2022 Draft SFMP that would allow for Lee County residents to have a choice in surgical care within their home county. The amount of patients outmigrating from Lee County would support a need for, at minimum, one or more ORs.

Lee County residents would significantly benefit from access to a second surgical option within the county. I fully support the requested petition to recognize a need for 2 ORs in the 2022 SMFP. An ambulatory surgery center with 2 ORs could be developed to increase access and choice of care for residents of Lee County. In addition, patients are provided quality outpatient surgical care at much lower rates in an ASC setting than they are in a hospital OR. This amounts to more cost-effective care being provided in an ASC setting, which is an option unavailable to Lee County residents locally today.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mary Florit".

Mary Florit

[Place on Letterhead]

May 25, 2021

North Carolina State Health Coordinating Council
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for an adjusted need determination for 2 additional operating room in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan*.

To Whom It May Concern:

My name is Cathi Von Canon and I am a resident of Lee County. . I am writing this letter to support the petition submitted by Pinehurst Surgical Clinic (“PSC”) for an adjusted need determination for 2 additional operating rooms (“OR”) in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan* (“SMFP”).

Historically there has been one hospital, Central Carolina Hospital, with 1 inpatient OR and 6 shared ORs in Lee County. Given its rural nature, the SMFP does not fully capture the need for additional ambulatory surgery services in Lee County. Over a four-year period, Lee County has experienced extensive outmigration for ambulatory surgery services. From 2016 to 2019, outpatient surgical volume at Central Carolina Hospital has declined, while outmigration from Lee County for outpatient surgical services has steadily increased. In 2019 alone, Lee County experienced an outmigration of 49.8 percent for ambulatory surgery services.

PSC believes it is important for Lee County patients to have access to surgery service close to home. In 2020 PSC had over 2,000 outpatient referrals from Lee County and these patients were primarily served in Moore County facilities. This outmigration places a burden on patients and their families. My patients have personally experienced difficulties due to the limited availability of outpatient surgery in Lee County.

I am not only a long time resident of Lee County but I am a Registered Nurse who worked at CCH for 27 years. I am saddened by the state of affairs of our current health care options. I no longer work for CCH and I most certainly would not choose CCH for my health care needs.

Due to the limited options for surgical care in Lee County, large numbers of patients are leaving Lee County for their surgery. This out-migration is not captured in the SMFP, and as a result,

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there is no need recognized in the 2022 Draft SFMP that would allow for Lee County residents to have a choice in surgical care within their home county. The amount of patients outmigrating from Lee County would support a need for, at minimum, one or more ORs.

Lee County residents would significantly benefit from access to a second surgical option within the county. I fully support the requested petition to recognize a need for 2 ORs in the 2022 SMFP. An ambulatory surgery center with 2 ORs could be developed to increase access and choice of care for residents of Lee County. In addition, patients are provided quality outpatient surgical care at much lower rates in an ASC setting than they are in a hospital OR. This amounts to more cost-effective care being provided in an ASC setting, which is an option unavailable to Lee County residents locally today.

Sincerely,
Cathi Von Canon RN
Lee County Resident

[Place on Letterhead]

[24 May 2021]

North Carolina State Health Coordinating Council
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for an adjusted need determination for 2 additional operating room in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan*.

To Whom It May Concern:

My name is [Tom Aguilar] and I am a [Lee County Resident]. I am writing this letter to support the petition submitted by Pinehurst Surgical Clinic (“PSC”) for an adjusted need determination for 2 additional operating rooms (“OR”) in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan* (“SMFP”).

Historically there has been one hospital, Central Carolina Hospital, with 1 inpatient OR and 6 shared ORs in Lee County. Given its rural nature, the SMFP does not fully capture the need for additional ambulatory surgery services in Lee County. Over a four-year period, Lee County has experienced extensive outmigration for ambulatory surgery services. From 2016 to 2019, outpatient surgical volume at Central Carolina Hospital has declined, while outmigration from Lee County for outpatient surgical services has steadily increased. In 2019 alone, Lee County experienced **an outmigration of 49.8 percent for ambulatory surgery services.**

PSC believes it is important for Lee County patients to have access to surgery service close to home. In 2020 PSC had over 2,000 outpatient referrals from Lee County and these patients were primarily served in Moore County facilities. This outmigration places a burden on patients and their families. My patients have personally experienced difficulties due to the limited availability of outpatient surgery in Lee County.

[ALL KNOWN OUTPATIENT SURGICAL PROCEDURES TO RELATIVES HAVE BEEN OUTSIDE OF LEE COUNTY DUE TO THE LIMITED OPTIONS FOR THIS AREA.]

Due to the limited options for surgical care in Lee County, large numbers of patients are leaving Lee County for their surgery. This out-migration is not captured in the SMFP, and as a result, there is no need recognized in the 2022 Draft SFMP that would allow for Lee County residents to

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have a choice in surgical care within their home county. The amount of patients outmigrating from Lee County would support a need for, at minimum, one or more ORs.

Lee County residents would significantly benefit from access to a second surgical option within the county. I fully support the requested petition to recognize a need for 2 ORs in the 2022 SMFP. An ambulatory surgery center with 2 ORs could be developed to increase access and choice of care for residents of Lee County. In addition, patients are provided quality outpatient surgical care at much lower rates in an ASC setting than they are in a hospital OR. This amounts to more cost-effective care being provided in an ASC setting, which is an option unavailable to Lee County residents locally today.

Sincerely,

[TOM AGUILAR]
[PRODUCTION MANAGER]
[CATERPILLAR INC.]

ADVANCED CARE FOR WOMEN
127 N Steel St
Sanford, NC 27330
919-776-7640

June 5, 2021

North Carolina State Health Coordinating Council
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for an adjusted need determination for 2 additional operating room in the Lee County, North Carolina OR service area in the 2022 State Medical Facilities Plan.

To Whom It May Concern:

My name is Paul Heimbecker, MD and I am a physician and my practice is in Sanford, NC. My specialty is Obstetrics and Gynecology and I have been practicing in Sanford 27 years. I am writing this letter to support the petition submitted by Pinehurst Surgical Clinic ("PSC") for an adjusted need determination for 2 additional operating rooms ("OR") in the Lee County, North Carolina OR service area in the 2022 State Medical Facilities Plan ("SMFP").

Historically there has been one hospital, Central Carolina Hospital ("CCH"), with 1 inpatient OR and 6 shared ORs in Lee County. Given its rural nature, the SMFP does not fully capture the need for additional ambulatory surgery services in Lee County. Over a four-year period, Lee County has experienced extensive outmigration for ambulatory surgery services. From 2016 to 2019, outpatient surgical volume at Central Carolina Hospital has declined, while outmigration from Lee County for outpatient surgical services has steadily increased. In 2019 alone, Lee County experienced an outmigration of 49.8 percent for ambulatory surgery services.

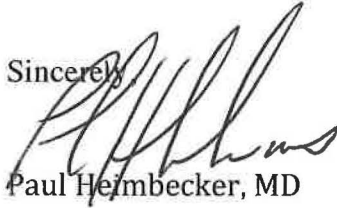
PSC believes it is important for Lee County patients to have access to surgery service close to home. In 2020 PSC had over 2,000 outpatient referrals from Lee County and these patients were primarily served in Moore County facilities. This outmigration places a burden on patients and their families. My patients have personally experienced difficulties due to the limited availability of outpatient surgery in Lee County.

This year I had to get surgical privileges at a hospital 30 miles away just to have more opportunity to do surgeries. The limitations for surgical times this past year have been primarily due to a unstaffed OR. There were service lines like dentistry and podiatry that were asked not to bring their surgeries to CCH.

Due to the limited options for surgical care in Lee County, large numbers of patients are leaving Lee County for their surgery. This out-migration is not captured in the SMFP, and as a result, there is no need recognized in the 2022 Draft SFMP that would allow for Lee County residents to have a choice in surgical care within their home county. The amount of patients out migrating from Lee County would support a need for, at minimum, one or more ORs.

My Lee County patients would significantly benefit from access to a second surgical option within the county. I fully support the requested petition to recognize a need for 2 ORs in the 2022 SMFP. An ambulatory surgery center with 2 ORs could be developed to increase access and choice of care for residents of Lee County. In addition, patients are provided quality outpatient surgical care at much lower rates in an ASC setting than they are in a hospital OR. This amounts to more cost-effective care being provided in an ASC setting, which is an option unavailable to Lee County residents locally today.

Sincerely,

A handwritten signature in black ink, appearing to read "P. Heimbecker", written over the word "Sincerely,".

Paul Heimbecker, MD

**PERKINS INVESTMENTS, LLC
P. O. BOX 525
SANFORD, NC 27331-0525**

May 24, 2021

North Carolina State Coordinating Council
North Carolina Division of Health Service Regulation
Healthcare Planning Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for an adjusted need determination for 2 additional operating room in the Lee County, North Carolina OR service area in the 2022 State Medical Facilities Plan

To Whom It May Concern:

My name is George R. Perkins, Jr. and I am a business owner, as well as homeowner, in Lee County. I am writing this letter to support the petition submitted by Pinehurst Surgical Clinic ("PSC") for an adjusted need determination for 2 additional operating rooms ("OR") in the Lee County, North Carolina OR service area in the 2022 State Medical Facilities Plan ("SMFP").

Historically there has been one hospital, Central Carolina Hospital, with 1 inpatient OR and 6 shared ORs in Lee County. Given its rural nature, the SMFP does not fully capture the need for additional ambulatory surgery services in Lee County. Over a four-year period, Lee County has experienced extensive outmigration for ambulatory surgery services. From 2016 to 2019, outpatient surgical volume at Central Carolina Hospital has declined, while outmigration from Lee County for outpatient surgical services has steadily increased. In 2019 alone, Lee County experienced an outmigration of 49.8 percent for ambulatory surgery services.

PSC believes it is important for Lee County patients to have access to surgery services close to home. In 2020 PSC had over 2,000 outpatient referrals from Lee County and these patients were primarily served in Moore County facilities. This outmigration places a burden on patients and their families. I personally know of patients that have experienced difficulties due to the limited availability of outpatient surgery in Lee County.

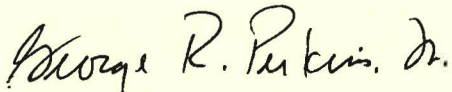
Having served on the local Hospital Board a number of years back, I have followed the patients' comments and valuation of health care extended to them. Today, I continue to hear negative remarks in regard to emergency room wait time, unsuccessful surgery, loss of staff (both doctors and nurses), under existing ownership policy. This is unacceptable in a growth city, where we need good and improved health care. I can cite many residents refusing care in this facility and going to other hospitals. This needs to be addressed.

Due to the limited options for surgical care in Lee County, large numbers of patients are leaving Lee County for their surgery. This out-migration is not captured in the SMFP, and as a result, there is no need recognized in the 2022 Draft SFMP that would allow for Lee County residents to have a choice in surgical

care within their home county. The amount of patents out-migrating from Lee County would support a need for, at minimum, one or more ORs.

Lee County residents would significantly benefit from access to a second surgical option within the county. I fully support the requested petition to recognize a need for 2 ORs in the 2022 MFP. An ambulatory surgery center with 2 ORs could be developed to increase access and choice of care for resident of Lee County. In addition, patients are proved a quality outpatient surgical care at much lower rates in an ASC setting than they are in a hospital OR. This amounts to more cost-effective care being provided in an ASC setting, which is an option unavailable to Lee County residents locally today.

Sincerely,



George R. Perkin, Jr.
CEO
Perkins Investments, LLC

GRPjr:dsh

June 30, 2021

Ms. Amy Craddock, PhD, Assistant Chief
NC DHHS, DHSR, Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Dear Ms. Craddock:

Please accept this letter as support for the petition submitted by Pinehurst Surgical Clinic to add a need determination for an operating room in Lee County in the 2022 State Medical Facilities Plan.

As FirstHealth Physician Group primary care physicians serving Lee County residents, we agree that local access to operating rooms and surgical services, which benefits our patients, is also a Basic Principle that governs the development of the State Medical Facilities Plans. When the standard methodology does not indicate a need to improve access, the petition process, which Pinehurst Surgical Clinic is utilizing, is the appropriate means to seek that improved access. Pinehurst Surgical Clinic has already increased access to surgical specialists in Lee County by partnering with FirstHealth to provide specialist coverage at the FirstHealth facility in Sanford.

Please let me know if I can be of any further assistance.

Sincerely,



Addison Zhang, M.D.
Internal Medicine



Jennifer Roehrs, D.O.
Family Practice



Vindya Jeyaretnam, D.O.
Family Practice

[Place on Letterhead]

July 26, 2021

North Carolina State Health Coordinating Council
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for an adjusted need determination for 2 additional operating room in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan*.

To Whom It May Concern:

My name is Stephanie Bailey and I am a Healthcare worker in Lee County, NC. I am writing this letter to support the petition submitted by Pinehurst Surgical Clinic ("PSC") for an adjusted need determination for 2 additional operating rooms ("OR") in the Lee County, North Carolina OR service area in the *2022 State Medical Facilities Plan* ("SMFP").

Historically there has been one hospital, Central Carolina Hospital, with 1 inpatient OR and 6 shared ORs in Lee County. Given its rural nature, the SMFP does not fully capture the need for additional ambulatory surgery services in Lee County. Over a four-year period, Lee County has experienced extensive outmigration for ambulatory surgery services. From 2016 to 2019, outpatient surgical volume at Central Carolina Hospital has declined, while outmigration from Lee County for outpatient surgical services has steadily increased. In 2019 alone, Lee County experienced an outmigration of 49.8 percent for ambulatory surgery services.

PSC believes it is important for Lee County patients to have access to surgery service close to home. In 2020 PSC had over 2,000 outpatient referrals from Lee County and these patients were primarily served in Moore County facilities. This outmigration places a burden on patients and their families. My patients have personally experienced difficulties due to the limited availability of outpatient surgery in Lee County.

My family and I seek medical treatment in Sanford but when surgery is warranted, we travel out of Sanford for our care.

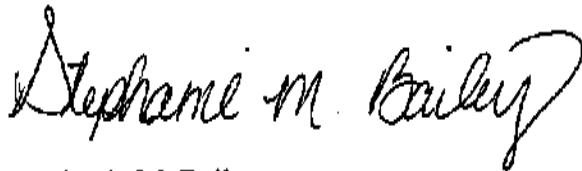
Due to the limited options for surgical care in Lee County, large numbers of patients are leaving Lee County for their surgery. This out-migration is not captured in the SMFP, and as a result, there is no need recognized in the 2022 Draft SFMP that would allow for Lee County residents

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to have a choice in surgical care within their home county. The amount of patients outmigrating from Lee County would support a need for, at minimum, one or more ORs.

Lee County residents would significantly benefit from access to a second surgical option within the county. I fully support the requested petition to recognize a need for 2 ORs in the 2022 SMFP. An ambulatory surgery center with 2 ORs could be developed to increase access and choice of care for residents of Lee County. In addition, patients are provided quality outpatient surgical care at much lower rates in an ASC setting than they are in a hospital OR. This amounts to more cost-effective care being provided in an ASC setting, which is an option unavailable to Lee County residents locally today.

Sincerely,

A handwritten signature in black ink that reads "Stephanie M. Bailey". The signature is written in a cursive style with a large initial 'S' and a long, sweeping tail.

Stephanie M. Bailey
Phlebotomist

Attachment B

Study Regarding Comparative Cost of Care

Medicare Payment Differentials Across Outpatient Settings of Care

Avalere Health | February 2016



Avalere Health
An Inovalon Company
1350 Connecticut Ave, NW
Washington, DC 20036

T | 202.207.1300
F | 202.467.4455

avalere.com

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The Physicians Advocacy Institute (PAI) provided funding for this analysis. Avalere maintained full editorial control.

EXECUTIVE SUMMARY

Medicare beneficiaries can receive the same services in different outpatient settings, yet various providers in those settings can receive different payments for that care and beneficiaries can face different cost-sharing amounts. For example, a Medicare beneficiary could receive a colonoscopy in the hospital outpatient department (HOPD), an ambulatory surgical center (ASC) or a physician office. Each setting of care has its own Medicare payment system as defined in statute and implemented by the Centers for Medicare & Medicaid Services (CMS), and can result in significant differences in Medicare payment rates for many services.¹

The purpose of this white paper is to assess Medicare payment differentials for episodes of care across the HOPD and physician office setting for three services commonly provided in outpatient settings: cardiovascular imaging, colonoscopy, and evaluation and management (E&M) services. We also examined payment differentials for the ASC setting as part of our colonoscopy analysis. We began by reviewing published literature for prior studies addressing this issue, and then performed our own analyses of episodes of care using Medicare claims data.

Our review of the literature reveals a general recognition that services provided in the HOPD setting usually have the highest payment rate, in comparison to the ASC or physician office settings for the same service. Prior publications also recognize challenges in comparing payment rates across settings of care, including potential differences in patient severity, variation in the unit of service used for payment in the payment system applicable to each setting, and lack of cost data for physician offices and ASCs. However, the studies that took steps to control for these variables still found that payment rates in the HOPD setting exceeded those in the ASC and physician office settings, with one study finding that differences in payments exceeded differences in costs.

Importantly, the previous studies mostly focused on payment differentials across settings for the individual service. In other words, with some exceptions, they measured differences in payments for a particular service when it was provided. However, it is possible that the setting where a physician performs services influences utilization and spending after the service, particularly the settings of post-service care. In order to further explore this concept, this white paper focuses on differences in Medicare spending for episodes of care beginning before and continuing after a particular colonoscopy, cardiac imaging procedure, or E&M visit.

¹ Unlike payment methodologies and rates among private payers, the Medicare payment system is transparent, with publically available information on costs and payment methodologies. For this reason, we focus on payment differentials for procedures that originate in outpatient settings of care in the Medicare program. Our episode definitions for cardiac imaging and colonoscopy include all costs during the episodes, not just outpatient costs.

After performing this comprehensive literature search, Avalere used Medicare claims data to perform primary research on Medicare payment rate differentials across settings of care for cardiac imaging procedures, colonoscopies, and E&M visits. In order to more accurately and comprehensively understand payment rate differentials across settings of care, we studied how payments and utilization differ across settings for episodes of care around a given procedure, not just for the procedure itself. We also adjusted these episodes for certain risk factors and patient demographics to better account for the total cost of care.

Two major takeaways emerged from our research. First, payments for services in the HOPD are higher for the primary service, and also for many related services during the episodes examined. Thus, the higher payments often associated with a HOPD procedure are not limited to the primary procedure, but can extend to related services performed adjacent to the primary procedure analyzed. Second, many HOPD-based procedures tend to be followed by a higher rate of additional procedures in the HOPD setting compared to office-based procedures. This difference in service mix may be attributable to a variety of factors which we discuss further in this paper. Together, these findings suggest that when care is initiated in the typically higher-paying HOPD setting, the services that follow also result in higher spending relative to when care is initiated in the office setting. Thus, the payment differential that begins with the initial service may extend and amplify throughout the entire episode.

For cardiac imaging procedures, we explored echocardiograms performed in the physician office and HOPD settings. We also examined a 3-day window, including the day of the procedure and one day before and after, and a 22-day window, which included the day of the procedure and seven days before and 14 days after. We examined all services performed for the patient within the episode windows. We found that cardiac imaging procedures result in higher payments across both episodes when performed in an HOPD compared to a physician's office. Average payments are 217 percent higher in the HOPD setting for a 3-day episode, and 80 percent higher in the HOPD setting for a 22-day episode.

For colonoscopies, we examined differences in total payments for procedures and for a 22-day colonoscopy episode, including all services 7 days before and up to 14 days after the colonoscopy. We found that payments for colonoscopy procedures are highest in the HOPD setting and least costly in the office setting. The same holds true for colonoscopy episodes of care; episode payments are highest in the HOPD and lowest in the office setting. Average payments are 35 percent higher for a 22-day colonoscopy episode performed in the HOPD setting.

Finally, for E&M procedures, we examined two profiles of E&M visits. The first profile examined E&M visits within seven days of a hospitalization, while the second profile examined new patient E&M visits. For both profiles, we examined all ambulatory payments within seven days following the E&M visit. We found that for both profiles, E&M visits that begin in the HOPD setting are associated with higher payments than E&M visits that begin in the office setting. Average payments for a 7-day episode following an E&M visit in the

HOPD are 22 percent and 29 percent higher than in the office, for Profiles 1 and 2, respectively.

Across all three analyses, we adjusted for the risk factors in Appendix VI.2, including patient demographics, CMS Hierarchical Condition Categories (CMS-HCCs), and certain procedure-specific stratifications. For cardiac imaging, adjusting for these risk factors explained 1 to 13 percent (depending on episode length) of the difference in payments between an office and HOPD. For colonoscopy, risk adjustment explained 9 to 27 percent (depending on episode length) of the difference in payments between an office and HOPD. And for E&M procedures, risk adjustment explained 17 to 24 percent (depending on episode type) of the difference in payments between an office and HOPD. These results suggest that differences in patient populations treated in the office and HOPD settings only account for a small portion of the observed differences in payments across settings.

There are several potential limitations to our study. First, we utilized administrative claims data that may not contain information about why a patient sought care at a certain type of facility. Second we examined a limited number of procedures and episode lengths and, although the procedures we examined are common, results may differ for other ambulatory services not examined or for episodes defined in a different manner. Additional limitations and further discussion can be found in Appendix IV.2.C.

BACKGROUND

Differences in payment rates for the same service have raised concerns that providers face incentives to provide care in costlier settings at potentially significant – and possibly unnecessary – expense to the Medicare program and beneficiaries. However, some have argued that higher payment rates for services provided in the HOPD are justified due to higher demands and regulatory burdens on hospitals, such as the need to provide emergency care, safety net care, and disaster preparedness and response. Additionally, patient severity at hospitals may be greater than in other outpatient settings, resulting in increased costs to hospitals for providing the same services.²

In recent years, stakeholders have shown increasing interest in addressing the tension between reducing incentives to provide care in more expensive settings while recognizing justifiable differences in costs across settings of care. For example, as discussed later in this paper, the Medicare Payment Advisory Commission (MedPAC), a non-partisan legislative branch agency providing Congress with advice on the Medicare program, has recently made a number of recommendations designed to equalize payment rates across settings of care for those services that can be safely provided outside of the hospital setting. While MedPAC's recommendations generally involve reducing HOPD payment rates to ASC/physician office levels for certain services, recent efforts by CMS to address payment

² American Hospital Association, "Site Neutral Payment Proposals Threaten Access to Care," available at www.aha.org/content/13/fs-siteneutral.pdf

disparities have thus far focused on reducing physician payment rates to the ASC/HOPD level for those relatively few services where the physician office setting receives the higher payment rate.³ Recently, as part of the Bipartisan Budget Act of 2015, also known as the Budget Deal, Congress mandated that, beginning in 2017, all off-campus physician practices and ASCs acquired by a hospital following enactment of the law in November 2015 no longer be reimbursed using the HOPD payment rates. While the law scales back the opportunity moving forward for physician offices and ASCs to become part of the hospital and receive higher payments than they received before acquisition, the law does not equalize payments across payment systems or otherwise address the overall incentives to provide care in more expensive settings noted by MedPAC and others.⁴

Before addressing current literature on the subject, it is important to understand the differences in payment methodologies across the relevant settings of care. Below, we provide a high-level summary of each payment system as determined by reference to applicable statutes, regulations, and CMS guidance.

Hospital Outpatient Department Payment System

Beginning in August of 2000, most services and items provided in the HOPD setting are paid for under the outpatient prospective payment system (OPPS). Under this system, CMS groups services described by Healthcare Common Procedure Coding System (HCPCS) codes into ambulatory payment classifications (APCs). Services within the same APC have similar cost and clinical characteristics and are paid the same amount. CMS packages integral services and items with the primary service in each APC. For example, contrast agents are packaged with the APC applicable to the associated imaging procedure provided to the patient. CMS assigns a relative weight to each APC reflecting the mean cost of services assigned to that APC. CMS determines the payment rate for each outpatient service by multiplying the relative weight for the applicable APC by the OPPS conversion factor, which is updated annually. The payment rate consists of two parts- the labor related portion and the non-labor related portion. To account for geographical differences in wages, CMS adjusts the labor related portion by the hospital wage index. Hospitals may qualify for additional payments in some cases, including pass-through payments for new technologies, outlier payments for extremely costly cases, and certain extra payments for cancer hospitals, children's hospitals, and sole community hospitals.⁵

³ For example, CMS proposed, but did not finalize, a policy that would cap physician payments to ASC/OPPS levels so that physician non-facility payment amounts would not exceed payments made for the same service provided in the facility setting. 78 Fed Reg. 74230, 74248 (Dec. 10, 2013).

⁴ Bipartisan Budget Act of 2015, available at <https://www.congress.gov/bill/114th-congress/house-bill/1314/text>

⁵ Social Security Act (SSA) § 1833(t); 42 C.F.R. Part 419; Medicare Claims Processing Manual, ch. 4. See also MedPAC Payment Basics: Outpatient Hospital Services Payment System, available at <http://www.medpac.gov/documents/payment-basics/outpatient-hospital-services-payment-system.pdf?sfvrsn=0>

Physician office

Medicare payment for physician services is based on the physician fee schedule, a list of payment rates for services as described by HCPCS codes. In setting the payment rate for each HCPCS code, CMS assigns relative value units (RVU) to three factors that affect physicians' costs: the amount of physician work involved, practice expenses, and malpractice/professional liability insurance. The work RVU, practice expense RVU, and malpractice RVU are each multiplied by separate geographic cost indexes to reflect differences in prices in different markets. The adjusted RVUs are summed and then multiplied by the physician fee schedule conversion factor, which is updated annually, in order to calculate the total payment rate. Unlike in the OPDS and ASC payment systems, payments for services are not usually "packaged" together in the physician payment system; providers generally receive a separate payment for each service provided.

Payments may be adjusted for various reasons, such as when the service is furnished by non-physician practitioners (downward adjustment) or if the physician provides services in underserved areas (upward adjustment). Use of payment modifiers may also result in payment adjustments. For example, most diagnostic procedures have a professional component, which covers physician interpretation of test results, and a technical component that covers the expenses of providing the diagnostic service. If the provider bills for the service "globally," he or she is reimbursed for interpretation of the results as well as for the use of space, equipment, supplies, and technical staff support used in actually performing the procedure. However, if the procedure itself is performed at another facility and the physician only interprets the results, he or she will bill for the procedure using modifier code "26" indicating that the physician is only billing for the professional component. The facility where the diagnostic service was actually performed would bill for the technical component.

It is important to note that physicians are paid for services they provide in the physician office, HOPD, and ASC settings. The work and malpractice RVUs are the same across all three settings of care. The practice expense RVU, however, varies depending on whether the service was provided in the physician office. When the service is provided in the physician office, the practice expense RVU is higher to reflect the fact that the physician incurred the full cost of providing that service. When the service is provided in the HOPD or ASC, the practice expense RVU is lower because the facility incurred part of the expenses and will receive an additional payment from Medicare to account for that expense. As a result, physicians themselves are paid more when they provide services in the physician offices, and less when they provide care at a facility. When a physician's service is provided in a facility, the beneficiary's cost sharing and overall cost of the service to the Medicare program will be based on both the physician's and the facility's payment. When the service is provided in the physician's office, the Medicare payment and beneficiary cost sharing is based on the payment under the physician fee schedule. For example, Medicare will provide a single payment to the physician for a clinic visit provided in the physician's office, while a visit that occurs in a HOPD-based physician office will

trigger both a payment to the physician and a payment to the HOPD, with beneficiaries being responsible for two copayments.⁶

Ambulatory Surgical Center (ASC)

For purposes of the Medicare program, an ASC is a “distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.”⁷ Beginning January 1, 2008, CMS implemented a revised payment system for ASCs, whereby payment for most services is set prospectively as a percentage of the OPPS payment rates. Medicare payment is made to ASCs for all surgical procedures except those that CMS determines may pose a significant safety risk to beneficiaries or that are expected to require an overnight stay when furnished in an ASC. Each year, CMS publishes updates to the list of procedures for which an ASC may be paid. As in the HOPD setting, the unit of payment for ASCs is the HCPCS code, with payments derived for each HCPCS from the OPPS APCs.

As in the OPPS, CMS determines the payment rate for each service by multiplying the relative weight for the applicable APC by the ASC conversion factor, which is updated annually. Although the relative weights assigned to APCs in the ASC payment system are based on the OPPS relative weights, the conversion factor used to convert the relative weights into payment amounts are different. The ASC conversion factor is lower than the OPPS conversion factor, resulting in lower ASC payment rates for the same service, reflecting findings by the Government Accountability Office (GAO) in a 2006 report that ASC costs are lower than HOPD costs across services.⁸ As in the OPPS, the labor portion of the ASC conversion factor is adjusted by the hospital wage index to account for geographic differences in costs.

Most products and services that are paid separately in the HOPD are also paid separately in the ASC, such as pass-through payments for new technologies and separately payable drugs and biologicals. CMS also uses alternate methods to establish payment rates for limited surgical and ancillary services, such as office-based procedures, device-intensive procedures, and separately payable facility costs of covered ancillary radiology services.⁹

⁶ SSA § 1848; 42 C.F.R. Part 414, subpart B; Medicare Claims Processing Manual, ch. 12, 23. See also MedPAC Payment Basics: Physician and Other Health Professionals Payment System, available at <http://www.medpac.gov/documents/payment-basics/physician-and-other-health-professionals-payment-system-14.pdf?sfvrsn=0>

⁷ 42 C.F.R. § 416.2.

⁸ Government Accountability Office, “Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient Payment System,” GAO-07-86 (2006), available at <http://www.gao.gov/products/GAO-07-86>

⁹ SSA § 1833(i), 42 C.F.R. Part 416, Medicare Claims Processing Manual, ch. 14. See also MedPAC Payment Basics: Ambulatory Surgical Center Services Payment System, available at <http://www.medpac.gov/documents/payment-basics/ambulatory-surgical-center-services-payment-system-14.pdf?sfvrsn=0>

LITERATURE REVIEW

Avalere searched peer-reviewed literature, published white papers, and policy briefs discussing differences in payment rates and utilization of services across ASCs, HOPDs and physician offices. Avalere also reviewed materials issued by MedPAC, as well as government reports, including publications by the Department of Health and Human Services (HHS) Office of Inspector General (OIG) and the GAO. Avalere focused its efforts on identifying documented differences in payment across settings of care for services that are safe and effective when performed in the physician office. Avalere targeted its research on publications from the past five years, but considered older articles for inclusion in the literature review if they appeared particularly relevant. Avalere selected five peer-reviewed articles and eight white papers and government reports for inclusion in the literature review based on the publications' relevance, timeliness, and strength of analysis.

Several articles document differences in payment rates across the HOPD, ASC, and physician office settings of care, as well as shifts in utilization for certain services from the physician office to HOPDs. For example, one study found that on average, HOPDs are paid 1.8 times more than ASCs and 3.6 times more than the office-related payment of the physician fee schedule.¹⁰ Some articles cited lack of data on costs of services in ASCs and physician offices as a significant obstacle in determining whether differences in payment rates are justified by differences in costs across these settings of care, including costs associated with patient severity. However, the studies that took steps to control for these variables still found that payment rates in the HOPD setting exceeded those in the ASC and physician office settings.

The policy options discussed in the published literature generally focus on neutralizing incentives for providing care in more expensive settings by capping HOPD rates for certain services at the rates paid to ASCs or physician offices. Both the OIG and MedPAC have recommended that CMS take steps to align payment rates for certain services that could safely be performed in physician office, ASC, or HOPD settings by reducing HOPD rates. However, to date, CMS has focused only on capping physician office payment rates to the HOPD payment rates for those services for which physician payments are higher than HOPD payments. In the 2014 physician fee schedule proposed rule, it proposed to cap physician payment rates at ASC/OPPS level for these services, but did not finalize the proposal after receiving overwhelmingly negative responses from commenters.¹¹ Additionally, CMS has a long-standing policy of capping payments for certain procedures designated as "office-based" at the physician office rate when performed in an ASC.¹²

¹⁰ Wynn et al., "Policy Options for Addressing Medicare Payment Differentials Across Ambulatory Settings," RAND Health (2011), pp. 2, 24 available at http://www.rand.org/content/dam/rand/pubs/technical_reports/2011/RAND_TR979.pdf

¹¹ 78 Fed Reg. 74230, 74248 (Dec. 10, 2013).

¹² 78 Fed. Reg. 74826, 75071 (Dec. 10, 2013).

Peer-Reviewed Literature

Avalere identified five articles from the peer-reviewed literature offering insight into payment and utilization differentials across the three relevant settings of care. A July 2014 *Health Affairs* policy brief by Cassidy highlighted key considerations for the development of a site-neutral payment system across outpatient settings of care.¹³ Cassidy observed that services that can safely be provided in a variety of settings are often paid by Medicare at dramatically different payment rates.¹⁴ Cassidy also noted challenges to equalizing payment rates across settings of care while properly accounting for differences in cost and patient mix across settings. For example, unlike hospitals, ASCs and physician offices do not submit detailed cost information to CMS, making it difficult to determine whether the lower payments under those payment systems relative to the OPSS payment system accurately reflects lower costs.¹⁵ Additionally, differences in payment systems across the settings of care make it challenging to compare the payment rate for a particular service across settings; while physician payments are generally paid per service rendered, ASC and hospital payments are “bundled” or packaged such that payment for a range of related services are packaged together.¹⁶ The unit of service used for payment therefore differs across settings of care, making comparisons difficult.¹⁷

The article also addresses the arguments made by some that higher payment rates to hospitals are necessary because hospitals provide services that ASCs and physician offices do not, such as 24-hour care, safety-net care to the uninsured and underinsured, and services during disasters.¹⁸

Two of the peer-reviewed articles identified by Avalere studied the migration of cardiologists from the physician office to the HOPD setting following reductions in physician payments for cardiac imaging services. Levin et al. investigated utilization trends between cardiology offices and HOPDs in echocardiography services following bundling of the add-on codes for spectral Doppler and color flow Doppler echocardiography into one single code for primary transthoracic echocardiography in 2009.¹⁹ The payment rate for the new bundled code was lower than the sum of the payment rates for the three separate codes. The authors found that the code bundling caused an immediate sharp decrease in the volume of echocardiography services performed in both the physician office and HOPD settings in 2009.²⁰ However, between 2010 and 2011, the volume of office procedures continued its decline while volume in the HOPD setting increased 32 percent.²¹ The

¹³ Cassidy, “Site-Neutral Payments,” *Health Affairs: Health Policy Brief* (July 24, 2014).

¹⁴ *Id.* at 1.

¹⁵ *Id.* at 5.

¹⁶ *Id.*

¹⁷ The Hollingsworth and Wynn publications controlled for this issue. In the Hollingsworth study, the authors used a 30 day claims window to capture all payments relating to a certain procedure. The Wynn study analyzed payment and utilization rates at five different levels of service aggregation in order to capture relevant data.

¹⁸ Cassidy at p. 5.

¹⁹ Levin et al. “The Diversion of Outpatient Echocardiography from Private Offices to Higher Cost Hospital Facilities: An Unanticipated Effect of Code Bundling.” *J Am Coll Radiol* 2014; 11:477-480.

²⁰ *Id.* at 478.

²¹ *Id.* at 478-79.

authors hypothesized that bundling caused many physician offices to close, resulting in a shift to the HOPD setting. The authors noted that this shift in site of service could create a problem for CMS because the “considerably higher” payments to hospitals would at least partially offset any savings from the code bundling.²²

An article by Ferrari et al. provided a history of payment systems and potential changes impacting cardiovascular imaging.²³ The authors compared payment rates in the physician office and HOPD setting since 2002, finding that between 2007 and 2012, physician payment for cardiac imaging decreased each year while OPPI payment increased each year starting in 2004 before leveling off in 2010.²⁴ The authors observed that “decreased payments for in-office imaging have driven many cardiologists into hospital employment, which may decrease incentives for ordering imaging tests and increase the difficulty of obtaining imaging.”²⁵ The authors also predicted that CMS will likely reduce OPPI payments for imaging procedures in the future.²⁶

With respect to urologic procedures, Hollingsworth et al. investigated claims for 22 common outpatient urologic procedures from 1998 to 2006 to determine differences in payment across sites of care.²⁷ The authors used a 30-day claims window to extract payment data for all services from the date of surgery to 30 days after the procedure. After applying a case-mix adjustment to account for differences in health status in the patients served across settings, the authors found that for all but two procedure groups, ASCs and physician offices received lower overall episode payments than HOPDs.²⁸ The authors also found that after accounting for differences in patient mix, physician offices received lower payments than ASCs, but the magnitude of the difference was small.²⁹ The authors identified outpatient facility payments as the most significant driver of the payment differential across sites of service.³⁰

The authors estimated that moving 50 percent of procedures examined from HOPDs to ASCs would save Medicare \$66 million annually.³¹ The authors concluded that their analysis supports policies “that encourage the provision of outpatient surgical care in less resource-intensive settings,” such as calculating payments based on costs in the least expensive settings of care or bundling payments to facilities and physicians, but that further research should focus on determining how indirect costs of treating patients are distributed across various settings of care.³²

²² *Id.* at 479.

²³ Ferrari et al. “Cardiovascular imaging payment and reimbursement systems: understanding the past and present in order to guide the future.” *JACC Cardiovasc Imaging* 2014 Mar; 7(3):324-32.

²⁴ *Id.* at 328-29.

²⁵ *Id.* at 330.

²⁶ *Id.* at 331.

²⁷ Hollingsworth et al. “Medicare payments for outpatient urologic surgery by location of care.” *J Urol.* 2012 Dec; 188(6): 2323–2327 (author manuscript).

²⁸ *Id.* at 4.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Id.* at 5.

Suskind et al. studied the effect the opening of an ASC in a healthcare market had on utilization and quality of outpatient urologic surgery procedures.³³ The authors performed a retrospective cohort study of Medicare beneficiaries who underwent urological procedures between 2001 and 2010. The markets in which these procedures were performed were classified into three groups: those with ASCs, those without ASCs, and those where ASCs were introduced.³⁴ The authors found that the rate of urologic surgeries performed in HOPDs declined in markets where ASCs were introduced from 221 to 214 procedures per 10,000 beneficiaries, while overall utilization remained stable. During the same timeframe, HOPD utilization increased in markets without or already having an ASC.³⁵ Furthermore, the authors found that the shift from the HOPD to the ASC setting of care in the markets where an ASC was introduced did not have any implications on quality of care as measured by mortality and hospital admission.³⁶ The authors concluded that ASCs could potentially improve efficiency in the delivery of urological procedures to Medicare beneficiaries, without leading to questionable increases in utilization.³⁷

Taken together, these studies indicate that differences in payment rates are correlated with shifts in sites of service to costlier settings of care. Furthermore, the Suskind article suggests that quality of care between HOPDs and ASCs is equal in the procedures studied. However, the articles also recognize a number of challenges when comparing payment rates and costs across settings, including potential differences in patient severity across settings, differences in the unit of payment across payment systems, and lack of cost data in the physician office and ASC settings. The Hollingsworth study controlled for patient severity and used a claims window to address the issue of differences in the payment unit across the payment settings. After controlling for these variables, the study still found that HOPDs received higher payment rates than ASCs and physician offices for most of the procedures studied, suggesting that the physician office and ASC settings are more cost-efficient than the HOPD setting.

MedPAC, OIG, and GAO Reports

Over the past decade, MedPAC has recommended site-neutral payment policies across outpatient settings in several reports to Congress. In its March 2004 report, MedPAC noted that different payment rates across outpatient settings did not appear to be related to differences in costs for some procedures, and recommended that the Secretary of HHS “evaluate whether shifts of surgical services among ambulatory settings are related to clinical reasons, financial incentives, patient preferences, or other factors.”³⁸

³³ Suskind et al. “Ambulatory surgery centers and outpatient urologic surgery among Medicare beneficiaries.” *Urology* 2014 Jul; 84(1):57-61.

³⁴ *Id.* at 58.

³⁵ *Id.* at 59.

³⁶ *Id.* at 61.

³⁷ *Id.*

³⁸ Medicare Payment Advisory Commission, “Ambulatory surgical center services: Assessing payment adequacy and updated payments.” In *Report to the Congress: Medicare Payment Policy*. Washington DC: MedPAC, March 2004, p. 199.

More recently, MedPAC has made specific recommendations with respect to a site-neutral payment policy across outpatient settings of care. In its March 2012 report, MedPAC found that in 2011, Medicare paid 80 percent more for a 15 minute E&M visit when provided in the HOPD compared to the physician office.³⁹ MedPAC hypothesized that the 6.7 percent growth in E&M visits provided at HOPDs in 2010, compared to the less than 1 percent growth during the same period in physician offices, could be due to the financial incentives created by this payment differential.⁴⁰ Specifically, MedPAC argued that the payment disparity creates an incentive for hospitals to purchase free standing physician offices and convert them to HOPDs without any change in the office's location or patient mix, and without regard to what may be best for patients.⁴¹ The result of a shift in billing from the physician office to the HOPD, MedPAC stated, is higher program spending and beneficiary cost sharing.⁴²

To address this payment disparity, MedPAC recommended equalizing the payment rates for E&M visits in HOPDs and physician offices by reducing HOPD payment rates to physician office rates. MedPAC further recommended that reducing hospital payment rates be phased in over a three-year period and that during the transition period, policymakers should take steps to limit the policy's impact on hospitals serving a disproportionate share of low-income patients.⁴³

In its June 2013 report to Congress, MedPAC assessed other services frequently performed in physician offices and ASCs that receive higher payment rates in the HOPD setting.⁴⁴ In its assessment, MedPAC acknowledged that for many services, equal payments between the various outpatient settings would not account for higher costs incurred by hospitals. For example, MedPAC explained that hospitals have higher costs than ASCs and physician offices because of their obligation to provide emergency services, more stringent regulatory and licensing requirements, and because they may treat sicker patients.⁴⁵

In order to address these differences in costs, MedPAC established criteria to identify services for which it would be appropriate to align payment rates across settings of care. MedPAC identified 66 groups of services provided in both HOPDs and other outpatient settings that are frequently provided in physicians' office (indicating that they are safe to perform and that payment is adequate in the physician office setting); are infrequently provided in the emergency department (indicating that such services are unlikely to have costs associated with providing emergency care); and for which average patient severity is no greater in the HOPD than in the physician office setting. Of these 66 groups of

³⁹ Medicare Payment Advisory Commission, "Hospital Inpatient and Outpatient Services." In *Report to the Congress: Medicare Payment Policy*. Washington DC: MedPAC, March 2012, p. 48.

⁴⁰ *Id.* at 51.

⁴¹ *Id.* at 72.

⁴² *Id.*

⁴³ *Id.* at 74-75.

⁴⁴ Medicare Payment Advisory Commission, "Medicare Payment Differences Across Ambulatory Settings." In *Report to the Congress: Medicare and the Health Care Delivery System*. Washington DC: MedPAC, June 2013, pp. 27-56.

⁴⁵ *Id.* at 28.

services, MedPAC identified 24 for which HOPD payment rates could be lowered to physician office rates, and 42 for which the HOPD payment rates could be reduced, but would remain higher than physician office rates. MedPAC found that equalizing payment rates for services in the former category and reducing the payment differential for services in the latter would on net reduce program spending and beneficiary cost sharing by \$900 million in one year.⁴⁶

MedPAC also considered less expansive policy alternatives, such as aligning payment rates between HOPDs and physician offices only for cardiac imaging services. MedPAC reasoned that focusing on cardiac imaging services would be particularly impactful given that payments for these services are significantly higher in HOPDs than in physician offices; MedPAC found that in 2013, Medicare paid 141 percent more for a level II echocardiogram in the HOPD setting than in the physician office setting.⁴⁷ MedPAC also considered the effects of equalizing payment rates for certain ambulatory surgical procedures between HOPDs and ASCs. MedPAC identified twelve procedures that met its criteria for payment alignment and estimated that reducing HOPD payment rates to ASC levels for these services would reduce program spending and beneficiary cost sharing by \$590 million in one year.⁴⁸

Although MedPAC explored a number of options for reducing payment differentials across outpatient settings, it ultimately did not recommend payment changes in the June 2013 report. However, in its March 2014 report, MedPAC recommended that Congress direct the Secretary of HHS to reduce or eliminate payment rates differentials between HOPDs and physician offices for the 66 groups of services identified in the June 2013 report, reducing the payment advantage hospitals may have. The Commission reasoned that incentives to shift care to the more expensive hospital setting when hospital-level care is not necessary must be addressed by reducing hospital payment rates. MedPAC argued that its recommendation would “reduce Medicare program spending, reduce beneficiary cost sharing, and create an incentive to care for patients in the most efficient setting appropriate for their condition.”⁴⁹

Like MedPAC, the OIG, which is tasked with deterring fraud, waste, and abuse in federal healthcare programs, has recommended that CMS reduce HOPD payment rates to those in less costly settings of care. In April 2014, OIG released a report conducted at Congressional request on the impact of different payment rates between HOPDs and ASCs on total Medicare expenditures.⁵⁰ OIG found that between 2007 and 2011, Medicare saved close to \$7 billion because ASC rates are lower than HOPD rates for the same outpatient surgical procedures, with \$2 billion saved by beneficiaries. The OIG’s analysis also found

⁴⁶ *Id.* at 27-30.

⁴⁷ *Id.* at 46-48.

⁴⁸ *Id.* at 48-51.

⁴⁹ Medicare Payment Advisory Commission, “Executive Summary.” In *Report to the Congress: Medicare Payment Policy*. Washington DC: MedPAC, March 2014, p. xiv.

⁵⁰ Office of Inspector General, “Medicare and Beneficiaries Could Save Billions If CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates,” A-05-12-00020 (April 2014).

that if CMS reduces HOPD payment rates for procedures approved for the ASC setting performed on no- or low-risk beneficiaries to match ASC payment levels, Medicare could save \$12 billion from 2012 through 2017.⁵¹

The OIG recommended that CMS seek legislation exempting reduced expenditures resulting from an HOPD payment cap from OPSS budget neutrality provisions in order to generate cost-savings for the Medicare program.⁵² The Medicare statute currently prevents CMS from generating savings to the program through changes to payment policies or payment rates. Rather, the law requires that any reductions in payments for some services be offset by increases in payments for other services, so that net payments to hospitals do not decrease year to year. If Congress enacted legislation to exempt payment neutrality cost savings from budget neutrality, OIG further recommended that CMS reduce OPSS payment rates for ASC-approved procedures for no-risk or low-risk beneficiaries.

CMS did not concur with the recommendations, observing the need for Congress to change the budget neutrality provisions in the statute and citing “circularity concerns” with the proposed methodology: because ASC payment rates are calculated as a lower percentage of the HOPD rates, it would be circular to then cap the OPSS rates at the OPSS-derived ASC rates. CMS also noted the lack of specific clinical criteria offered by OIG for distinguishing patients’ risk levels.⁵³ OIG responded that it continued to recommend that CMS draft and submit for review legislation that would exempt lower expenditures as a result of an OPSS payment cap from budget neutrality provisions, and that CMS was in the best position to determine a method for identifying low and no-risk patients.⁵⁴

More recently, in December 2015, the GAO released a report on the vertical consolidation of hospitals and physicians from 2007 through 2013 and the associated effect on E&M visit volume in hospitals.⁵⁵ Specifically, the GAO examined the extent to which hospitals are purchasing physician offices (ie, vertical integration) and the volume of E/M services performed by physician offices and HOPDs, the latter of which receives a higher Medicare payment rate compared to the physician office. GAO used a combination of American Hospital Association (AHA) survey data and Medicare claims data to conduct its review. In its report, GAO found that from 2007 through 2013 the number of vertically consolidated physicians nearly doubled, with faster growth in more recent years. GAO also found that the proportion of E/M office visits performed in HOPDs, instead of physician offices, was generally greater in counties with higher levels of vertical consolidation, even after adjusting for the health status of beneficiaries in those counties. Given these findings, GAO concluded that Medicare is likely overpaying for E/M visits and recommended Congress consider “directing the Secretary of the Department of Health and Human Services (HHS) to equalize payment rates between settings for E/M office visits—and other services the

⁵¹ *Id.* at i-ii.

⁵² *Id.* at 7-8.

⁵³ *Id.* at 8.

⁵⁴ *Id.*

⁵⁵ Government Accountability Office, “Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform,” GAO-16-189 (December 2015).

Secretary deems appropriate—and to return the associated savings to the Medicare program.”

Rand Corporation Studies

In 2011, the Rand Corporation published a report discussing policy options for addressing Medicare payment differentials across outpatient settings of care. The 2011 report was the final phase of a three-phase study commissioned by the Assistant Secretary of Planning and Evaluation of HHS. In the first phase of the study, published in 2008, the authors compared OPPS and ASC payment rates to non-facility practice expense RVUs or technical component rates under the physician fee schedule. Using data analyses where possible and structured interviews with providers, the authors also studied cost differences between settings while noting the difficulty of measuring and comparing costs across settings given available data sources. However, the authors ultimately concluded that payment differentials between HOPDs and ASCs/physician offices did not appear justified by cost differences between the settings of care.⁵⁶

In the second phase of the study, the authors measured differences in payments and patterns of care for nine high volume procedures. In this phase, the authors controlled for differences in the unit of payment across settings of care. For example, under the physician fee schedule, physicians are generally paid on a “per-service” basis, while in the ASC and HOPD settings, related services are generally packaged and paid for together. Differences in payment rates and patterns of care were measured at five different levels of service aggregation in order to accurately compare payments for services across settings of care. The authors found that standardizing payment units reduced the payment differential for some procedures, but that large differentials in payments across settings of care still remained.⁵⁷

In phase three, the authors updated the phase two results to account for changes in OPPS packaging policies and ASC coverage and payment policies. The authors also measured the overall payment differential between HOPDs, physician offices and ASCs, finding that in 2011, HOPDs were paid on average 1.8 times more than ASCs and 3.6 times more than the office-related portion of physician fee schedule payments for services in physician offices.⁵⁸ However, the authors again observed that the cost of providing services in each setting is “even more opaque” than the payment differentials, limiting the ability to assess cost differences across settings.⁵⁹

The authors discussed a number of policy considerations and potential ways to improve the value of services provided in ambulatory settings, including tying payment differentials to justifiable cost differences between settings (creating neutral incentives in terms of

⁵⁶ Wynn et al. at pp. 18-19, 71.

⁵⁷ *Id.* at 21.

⁵⁸ *Id.* at 2, 24.

⁵⁹ *Id.* at 3.

where care is delivered); basing payment on the amount payable in the least costly setting (creating incentives to shift care to the most efficient setting); and paying for services provided in hospital off-campus clinics at physician office or ASC rates. The authors also discussed policies that would increase uniformity in payment units across settings of care, such as packaging the same services into the same payment unit for all settings.⁶⁰

Oncology Site of Care Studies

In March 2012, the Community Oncology Alliance commissioned Avalere to analyze commercial health plan data to determine differences in total cost of care based on site of service for chemotherapy and radiation therapy.⁶¹ Avalere analyzed over 26,000 episodes for 22,204 individual cancer patients. The study compared average total episode costs in the physician's office and HOPDs, and controlled for the age, gender, and prior cancer history of the patients studied. The results suggested that chemotherapy treatment in the HOPD setting costs on average 24 percent more than in the physician office, with the average cost differences varying based on type of cancer.⁶² Additionally, Avalere found that chemotherapy episode costs in the physician office were lower than in the HOPD regardless of the length of the episode.⁶³ On the other hand, HOPD-managed patients receiving radiation therapy had slightly lower costs than office-managed patients.⁶⁴ Avalere did caution, however, that its model did not control for other factors that could influence total cost of care such as mortality and morbidity, and therefore the results should be interpreted with these limitations in mind.⁶⁵

In May 2013, the Moran Company issued a memorandum describing preliminary results of an analysis commissioned by the US Oncology Network, Community Oncology Alliance, and ION Solutions regarding shifts in site of service for chemotherapy from the physician office to the HOPD.⁶⁶ The memo highlighted key interim findings, including that the analysis supported the hypothesis that some Medicare fee for service (FFS) chemotherapy utilization shifted from the physician office to the HOPD from 2005 to 2011. Specifically, the analysis found that the proportion of FFS chemotherapy administration procedures performed in the HOPD rose from 13.5 percent in 2005 to 33 percent in 2011, while the proportion of procedures performed in the physician office fell from 86.5 percent to 67 percent over the same time period. The analysis noted that over the period of time studied, physician payment rates for chemotherapy services remained relatively flat while HOPD payment increased.

⁶⁰ *Id.* at 72.

⁶¹ Avalere Health, "Total Cost of Cancer Care by Site of Service: Physician Office vs. Hospital Outpatient" (2012).

⁶² *Id.* at 2.

⁶³ *Id.*

⁶⁴ *Id.* at 16.

⁶⁵ *Id.* at 2.

⁶⁶ The Moran Company, "Results of Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee-for-Service Beneficiaries," (preliminary results) (May 2013).

Summary

This review of the literature suggests that Medicare payment is generally higher in the HOPD than in the ASC or physician office settings for the same service, while acknowledging that the costs of providing the same service are generally higher in the HOPD than in the other two outpatient settings. The literature also documents shifts in sites of care for certain outpatient services to the HOPD setting that correlate with changes in payment rates in clinical areas such as cardiovascular imaging and oncology services. While the payment differential varies based on the type of service provided, one study found that on average, HOPDs were paid 1.8 times more than ASCs and 3.6 times more than the office-related portion of physician fee schedule payments for services in physician offices in 2011.⁶⁷

Most of the publications reviewed include a discussion of the challenges in comparing costs and payment rates across settings of care. Most frequently mentioned are the lack of cost data for ASCs and physician offices; potential differences in patient severity across the settings of care; and the different payment methodologies, specifically differences in the unit of measurement for reimbursable services. However, the Hollingsworth and Rand studies both found that HOPD payment rates remained higher than those in the other settings even when controlling for patient mix and unit of payment.

A number of stakeholders, such as MedPAC and the OIG, have expressed concern that these payment differentials discourage providers from supplying care in the most cost-efficient setting, and the GAO has suggested that Medicare's reimbursement of E&M services at different payment rates across different settings is "inconsistent with Medicare's role as an efficient purchaser of healthcare services."⁶⁸ The policy recommendations suggested by MedPAC OIG and GAO involve lowering HOPD payment rates for services that can be safely performed outside of the hospital setting. This policy suggestion would not result in increased payments to physicians, but would presumably diminish incentives to provide care in the HOPD for these services. According to MedPAC and OIG analyses, reducing or eliminating payment differentials across outpatient settings of care would result in substantial savings to the Medicare program and beneficiaries.

Some argue that costs of providing care are higher in the hospital setting for justifiable reasons, such as the need to provide emergency care and more stringent regulatory requirements, and that payment rates should reflect these cost differences. The authors of the RAND publications discussed a number of policy options that incorporate the issue of variances of cost, including options in which payment rates would account for justifiable differences in costs across settings of care and options in which payment rates would be based on the lowest cost setting. The latter option would encourage providers to provide care in the least costly setting, while the former would create neutral incentives with respect to site of care. Under either scenario, incentives to provide care in more expensive settings

⁶⁷ Wynn et al. at pp. 2, 24.

⁶⁸ Government Accountability Office, "Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform," GAO-16-189 (December 2015).

would be reduced, likely benefitting physician offices as they are generally the least costly site of care.

DATA ANALYSIS

After reviewing the literature, we analyzed Medicare claims data to ascertain differences in Medicare payment rates for episodes across outpatient settings of care. We studied three types of procedures/services: cardiac imaging, colonoscopy, and evaluation and management (E&M) services. While our literature review showed instances in which both payments and costs for individual procedures vary based on the site of care, there was little evidence on how payments compared across episodes. The purpose of this data analysis was to examine how payments and utilization of additional services vary across settings of care in a period of time around the procedures and services themselves.

For all three types of services that we analyzed, there may be significant variation in treatment patterns and treatment intensity, and therefore different patterns of how risk factors affect Medicare spending. In particular, we stratified models that estimated the effects of setting of care on expenditures as follows:

- Colonoscopy: Diagnostic colonoscopy; Screening colonoscopy
- Cardiac Imaging: Imaging without probe; Imaging with esophageal probe; Other cardiac ultrasound
- E&M services: Visit for an acute condition; visit for a chronic condition

In the analyses described below, including “unadjusted” results, we standardized expenditures across the strata within each service type because of differences across settings in the proportions of these services provided. Unstandardized unadjusted expenditures would have differences across settings due to these differences in the specific services within each of these three groups rather than due to payment policies and episode utilization patterns.

Cardiac Imaging Analysis

The purpose of this analysis was to assess the difference in Medicare payments for cardiac imaging services across the office and HOPD settings of care over an episode of time. We examined payments both for the cardiac imaging services themselves, as well as total payments over each episode window (inclusive of outpatient, inpatient, skilled nursing facility, home health, hospice, and durable medical equipment spending).

a. Episode Generation Methodology

In approaching generating cardiac imaging episodes, we began by identifying a set of cardiac imaging services to include in our analysis. We decided to examine the Healthcare Common Procedural Coding System (HCPCS) codes in three of Medicare’s Ambulatory

Payment Classifications (APCs) as of 2012: Level 1, Level 2, and Level 3 echocardiograms. These HCPCS codes are presented in **Table 1** below. With regard to frequency of these codes, HCPCS code 93306 (Transthoracic Echocardiography with Image Documentation, Complete) represented 88 percent all cardiac imaging HCPCS codes examined.

Table 1. Echocardiogram HCPCS Codes Included in Analysis

Target HCPCS	HCPCS Description	APC Description
76825	Echo exam of fetal heart	Level I Echocardiogram Without Contrast
76826	Echo exam of fetal heart	Level I Echocardiogram Without Contrast
93308	TTE Follow-up or Limited	Level I Echocardiogram Without Contrast
93304	Echo transthoracic	Level II Echocardiogram Without Contrast
93306	TTE w/ doppler complete	Level II Echocardiogram Without Contrast
93307	TTE w/o doppler complete	Level II Echocardiogram Without Contrast
93313	Echo transesophageal	Level II Echocardiogram Without Contrast
93315	Echo transesophageal	Level II Echocardiogram Without Contrast
93350	Stress TTE only	Level II Echocardiogram Without Contrast
93303	Echo transthoracic	Level III Echocardiogram Without Contrast
93312	Echo transesophageal	Level III Echocardiogram Without Contrast
93316	Echo transesophageal	Level III Echocardiogram Without Contrast
93318	Echo transesophageal intraop	Level III Echocardiogram Without Contrast
93351	Stress TTE complete	Level III Echocardiogram Without Contrast

Note: we excluded from our analysis the fetal echocardiogram codes 76825 and 76826

We chose to utilize both a narrow and a broad window for the cardiac imaging analysis. The narrow window was a 3-day episode, which included all costs the day of the cardiac imaging procedure, as well as one day before and one day after. The broad window was a 22-day episode, including all costs the day of the cardiac imaging procedure and 7 days before and 14 days after. For purposes of creating episodes, we grouped together all cardiac imaging procedures that occurred within +/- 1 day of each other and counted it as a single episode. We allowed episode windows for the same patient to overlap as long as the target cardiac imaging procedures themselves were deemed separate.

We constructed these episodes using a 5 percent sample of Medicare claims data from 2012, and included in our episode payments for all outpatient hospital, physician, inpatient, skilled nursing facility (SNF), home health, hospice, and durable medical equipment services. If an inpatient hospital or SNF stay occurred during the episode window, we included the entire payment for the stay in our episode (i.e., we did not prorate payment for the inpatient or SNF stays). We excluded from our analysis both patients with End Stage Renal Disease (ESRD) and those who died during the year of our analysis (2012).

We only included in our analysis cardiac imaging services performed in the office and hospital outpatient settings, and excluded cardiac imaging performed in all other settings including the inpatient setting. Recognizing that differences in patient demographics, conditions, and other variables can contribute to differences in utilization and payments across settings of care, we developed a risk adjustment model as part of this analysis to account for certain patient characteristics and differences in practice patterns across settings. As for all three types of procedure episodes, we also excluded outlier episodes (the top 0.5 percent of episodes based on total payments) because of poor performance of risk adjustment models for these episodes. The following patient episodes were included in our analysis:

Table 2. Cardiac Imaging Episode Counts

Starting Setting of Cardiac Imaging Procedure	Number of Episodes²	Percent of Total
Office	140,231	39%
Hospital Outpatient (HOPD)	96,238	27%
All Other Settings ¹	122,321	34%
Total	358,790	100%

¹ Cardiac imaging episodes in settings other than the office or hospital outpatient department were excluded from our analysis

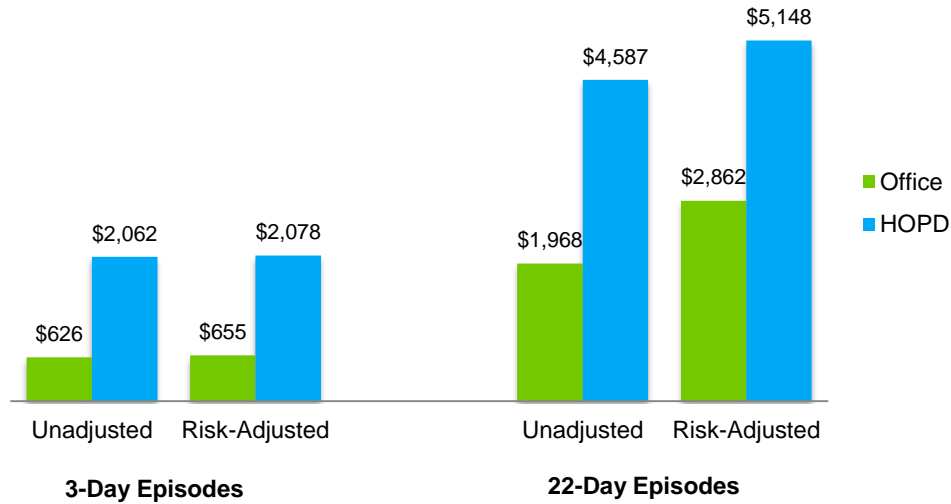
² Of the 140,231 office episodes, 120,291 (86 percent) were for patients with only one episode per year. Of the 96,238 HOPD episodes, 74,722 (78 percent) were for patients with only one episode per year.

Additional discussion of the risk adjustment methodology, including the adjustment factors included in our models and the predictive performance of the models, can be found under the Risk adjustment methodology discussion in Appendix VI.2.

b. Results

We find that average cardiac imaging episode payments are higher when a cardiac imaging procedure begins in the hospital outpatient department (HOPD) compared to the office setting. These findings are true for both 3-day episodes and 22-day episodes. Average risk adjusted payment in the HOPD is \$1,423 (or 217 percent) higher for a 3-day episode and \$2,286 (or 80 percent) higher for a 22-day episode.

Figure 1. Average Payment for Cardiac Imaging Episodes



Note: 95% confidence intervals of estimated average unadjusted and risk adjusted payments not shown in Figure 1.

Table 3. Average Payment for Cardiac Imaging Episodes (Additional Detail)

Colonoscopy Setting	Unadjusted: All Episodes	Unadjusted: Top 0.5% Outliers Removed	Unadjusted Payment Relative to Office	Risk-Adjusted: Top 0.5% Outliers Removed	Risk-Adjusted Payment Relative to Office
3-Day Episodes					
Office	\$641 (\$612, \$672)	\$626 (\$597, \$655)	\$0	\$655 (\$627, \$683)	\$0
HOPD	\$2,198 (\$2,173, \$2,224)	\$2,062 (\$2,038, \$2,086)	+\$1,436 (+\$1,398, +\$1,474)	\$2,078 (\$2,053, \$2,103)	+\$1,423 (+\$1,387, +\$1,459)
22-Day Episodes					
Office	\$2,001 (\$1,940, \$2,061)	\$1,968 (\$1,905, \$2,031)	\$0	\$2,862 (\$2,785, \$2,940)	\$0
HOPD	\$4,722 (\$4,663, \$4,780)	\$4,587 (\$4,522, \$4,652)	+\$2,619 (+\$2,528, +\$2,709)	\$5,148 (\$5,081, \$5,215)	+\$2,286 (+\$2,191, +\$2,381)

Note: 95% confidence intervals of estimated average unadjusted and risk adjusted payments shown in parentheses. Excludes top 0.5% of outliers based on total episode spending.

Table 4. Frequency of Other Services within Cardiac Imaging Episodes and Associated Payments

	Percentage of Episodes with Other Events/Services		Average Episode Payment Per Patient When Service Was Utilized (Unadjusted)	
	Office	HOPD	Office	HOPD
3-Day Episodes				
Ambulatory Visits	100%	100%	\$576 (\$568, \$583)	\$1,911 (\$1,889, \$1,933)
Inpatient Stays	< 1%	2.1% (1.9%, 2.2%)	...	\$7,257 (\$6,990, \$7,525)
Durable Medical Equipment	< 1%	< 1%
Skilled Nursing Facility	< 1%	< 1%
Home Health	< 1%	< 1%
22-Day Episodes				
	Office	HOPD	Office	HOPD
Ambulatory Visits	100%	100%	\$1,372 (\$1,342, \$1,402)	\$3,069 (\$3,034, \$3,103)
Inpatient Stays	4.7% (4.3%, 5.1%)	11.6% (11.3%, 11.9%)	\$12,050 (\$11,684, \$12,417)	\$12,458 (\$12,167, \$12,750)
Durable Medical Equipment	1.1% (0.9%, 1.2%)	2.9% (2.7%, 3.0%)	\$305 (\$255, \$356)	\$341 (\$284, \$397)
Skilled Nursing Facility	< 1%	1.2% (1.1%, 1.3%)	...	\$4,236 (\$3,898, \$4,574)
Home Health	< 1%	< 1%

Notes: 95% confidence intervals of estimated average unadjusted and risk adjusted payments shown in parentheses. Average payments per patient when service is utilized exclude top 0.5% of episode outliers.

c. Discussion

The unadjusted difference between the Office and the HOPD for a 3-day cardiac imaging episode is \$1,436. After applying our risk adjustment methodology, the difference between the Office and the HOPD falls to \$1,423. The difference between these differences (\$13, or less than 1 percent) is the portion of the payment differential between settings that can be explained by the factors included in our risk adjustment models.

Several factors may be contributing to higher episode payments associated with a cardiac imaging services provided in the HOPD compared to the Office setting. Payment for ambulatory services, including but not limited to the cardiac imaging service itself, is higher on average in the HOPD setting. Except for ambulatory visits, payment by setting is similar

over the 22-day episode, suggesting that differences in total episode payments are driven by whether there is utilization after the cardiac imaging service rather than intensity of that utilization. The 3-day episode window is generally too short to include much additional service utilization beyond the ambulatory visits themselves, which include the cardiac imaging procedures and other hospital outpatient and physician services.

There are several factors that contribute to these differences across settings. First, Medicare uses different payment systems for different settings of care to reflect differences in costs across settings. Second, facility fees for services in the HOPD settings are meant to cover the payments associated with operating the facilities. Higher-cost settings can incur higher fixed and variable costs, even if the procedure is similar across settings of care.

Third, there may be differences in patients who receive a cardiac imaging service in the HOPD setting compared to the office setting. Our risk adjustment models attempt to control for differences in patient demographics and clinical severity. As discussed further Appendix VI.2, our risk adjustment model explains a portion of the difference in payments for cardiac imaging episodes in the HOPD vs. office settings. The remaining, unexplained variation is due to differences in payment rates and service utilization between settings, and patient characteristics not accounted for in our risk adjustment models.

Colonoscopy Analysis

The purpose of this analysis was to assess differences in colonoscopy episodes across the physician office, ASC and HOPD settings of care. We examined both the payments associated with the colonoscopy, as well as the average payments made for all procedures within a window of time before and after the colonoscopy.

a. Episode Generation Methodology

To conduct a comparison of colonoscopy episode payments across settings, Avalere utilized the definition of a colonoscopy episode from prior work conducted on the subject by the High Value Health Care Project,⁶⁹ which developed specifications for measuring resource use within a 22-day window surrounding a colonoscopy. The episode includes all physician, outpatient, and ancillary services (such as clinical laboratory tests and durable medical equipment) received by a patient in the 7 days prior to the colonoscopy, the day of the colonoscopy, and 14 days following the colonoscopy. In addition, we included all inpatient and SNF stays, and home health, hospice, and DME claims. If the inpatient or SNF stay began or occurred during the episode timeframe, we included the entire payment for the stay in the episode.

⁶⁹ Brennan, Niall J. et. al., "Defining an Episode of Care for Colonoscopy: Work of the High Value Health Care Project Characterizing Episodes and Costs of Care." *Gastrointestinal Endoscopy Clinics of North America*, 20 (2010) 735–750. Available at <http://www.ncbi.nlm.nih.gov/pubmed/20889075>.

For purposes of comparison, we replicated this analysis for a 61-day window, with a 30-day pre-window and a 30-day post-window. We present a brief summary of these additional results for the colonoscopy analysis in Appendix VI.2.

Our patient population included patients who received a colonoscopy (Healthcare Common Procedure Coding System (HCPCS) codes 45378, 45380, 45383, 45384, 45385, G0105, or G0121) during the episode window. We excluded certain types of patients that may have different treatment pathways than other patients receiving a colonoscopy. These include active cancer, end-stage renal disease, organ transplant, and HIV/AIDS patients. Consistent with the episode definition used by Brennan et al.,⁷⁰ we also excluded patients with ulcerative colitis, Crohn’s disease, or inflammatory bowel disease who were known to have such conditions prior to the colonoscopy window.

For this analysis, we used a 5 percent sample of Medicare claims data from 2012, including both physician and outpatient claims. In creating the episodes, we also pulled 2012 Medicare claims for inpatient, skilled nursing facility, home health, hospice, and durable medical equipment services. Recognizing that differences in patient demographics, conditions, and other variables can contribute to differences in utilization and payments across settings of care, we developed a risk adjustment model as part of this analysis to account for certain patient characteristics and differences in practice patterns across settings. As for all three types of procedure episodes, we also excluded outlier episodes (the top 0.5 percent of episodes based on total payments) because of poor performance of risk adjustment models for these episodes. The following patient episodes were included in our analysis:

Table 5. Colonoscopy Episode Counts

	Number of Episodes ²	Percent of Total
Type of Episode		
Diagnostic Colonoscopies	71,221	56%
Screening Colonoscopies	54,553	43%
Both Performed on Same Day	1,743	1%
Total	127,517	100%
Setting of Starting Colonoscopy		
Office	4,652	4%
Ambulatory Surgical Center	50,171	39%
Hospital Outpatient	58,842	46%
All Other Settings ¹	13,852	11%
Total	127,517	100%

⁷⁰ *Id.*

¹ Colonoscopy episodes in settings other than the office, hospital outpatient department, or ASC were excluded from our analysis.

² Of the 4,652 office episodes, 4,445 (96 percent) were for patients with only one episode per year. Of the 50,171 HOPD episodes, 48,494 (97 percent) were for patients with only one episode per year. Of the 58,842 HOPD episodes, 56,165 (96 percent) were for patients with only one episode per year.

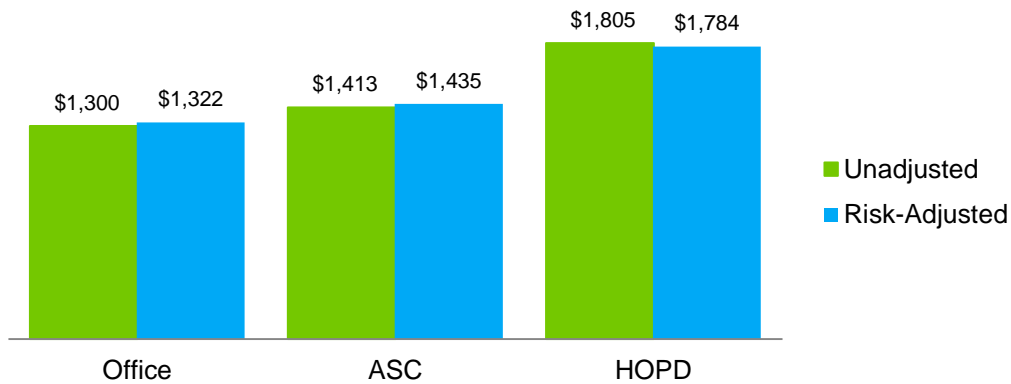
Note: there were an additional 30,948 episodes excluded from our analysis either because they were performed in a setting other than the office, ASC, or HOPD settings, or because a patient received more than one colonoscopy within a 3-day time-period in different settings, making it unclear which setting should be considered the "episode setting".

Additional discussion of the risk adjustment methodology, including the adjustment factors included in our models and the predictive performance of the models, can be found under the risk adjustment methodology discussion in Appendix VI.1.

b. Results

Below are the results of our analyses, comparing average payments for a colonoscopy episode in the physician office, ASC, and HOPD settings. These episodes encompass all types of colonoscopy included in our analysis, including both diagnostic and screening colonoscopies.

Figure 2. Average Payment Per 22-Day Colonoscopy Episode



Note: 95% confidence intervals of estimated average unadjusted and risk adjusted payments not shown in Figure 2.

Table 6. Average Payment for 22-Day Colonoscopy Episodes

Colonoscopy Setting	Unadjusted: All Episodes	Unadjusted: Top 0.5% Outliers Removed	Unadjusted Payment Relative to Office	Risk-Adjusted: Top 0.5% Outliers Removed	Risk-Adjusted Payment Relative to Office
Office	\$1,354 (\$1,298, \$1,411)	\$1,300 (\$1,262, \$1,338)	\$0	\$1,322 (\$1,289, \$1,354)	\$0
ASC	\$1,453 (\$1,437, \$1,470)	\$1,413 (\$1,402, \$1,425)	+\$113 (+\$73,+\$153)	\$1,435 (\$1,425, \$1,446)	+\$114 (+\$80,+\$148)
HOPD	\$1,917 (\$1,892, \$1,942)	\$1,805 (\$1,792, \$1,817)	+\$505 (+\$464,+\$545)	\$1,784 (\$1,774, \$1,794)	+\$462 (+\$428,+\$496)

Notes: 95% confidence intervals of estimated average unadjusted and risk adjusted payments shown in parentheses. Excludes top 0.5% of outliers based on total episode spending.

Table 7. Frequency and Associated Payments of Other Services within the Colonoscopy Episodes (Unadjusted)

	Percentage of 22-Day Episodes with Other Events/Services			Average 22-Day Episode Payment per Patient When Service Was Utilized (Unadjusted)		
	Office	ASC	HOPD	Office	ASC	HOPD
Inpatient Stays	1.0% (0.7%, 1.3%)	0.8% (0.8%, 0.9%)	1.6% (1.5%, 1.7%)	\$6,669 (\$6,014, \$7,325)	\$6,701 (\$6,444, \$6,958)	\$6,478 (\$6,315, \$6,640)
Durable Medical Equipment	6.9% (6.2%, 7.7%)	7.3% (7.0%, 7.5%)	9.7% (9.5%, 10.0%)	\$223 (\$173, \$273)	\$214 (\$199, \$228)	\$231 (\$217, \$246)
Skilled Nursing Facility	< 1%	< 1%	< 1%	n/a	n/a	n/a
Home Health	< 1%	< 1%	< 1%	n/a	n/a	n/a

Notes: 95% confidence intervals of estimated average unadjusted and risk adjusted payments shown in parentheses. Excludes top 0.5% of outliers based on total episode spending.

c. Discussion

The total payment for 22-day colonoscopy episodes (**Table 6**) after adjusting for risk factors is highest in the HOPD setting (\$1,784), second highest in the ASC setting (\$1,435), and lowest in the physician office setting (\$1,322).

The unadjusted difference between the Office and the HOPD for a 22-day colonoscopy episode is \$505. After applying our risk adjustment methodology, the difference between the Office and the HOPD drops to \$462. The difference between these differences (\$43, or 9 percent) is the portion of the payment differential between settings that can be explained by the factors included in our risk adjustment models.

We find that unadjusted payment on inpatient stays is similar across all three settings (**Table 7**). Given the low rate of hospitalizations during the episodes (1.0 percent for office-based episodes, 0.8 percent for ASC-based episodes, and 1.6 percent for HOPD-based episodes), and given that inpatient payments during the episode are similar across all three settings, we conclude that inpatient payments are not a driver of differences in total episode payments across settings, and that the colonoscopies themselves are more likely driving these differences. We note that only a small portion of episode payments were on durable medical equipment, skilled nursing facility, home health, and hospice stays. This is attributable to low utilization of these services within our episodes.

We also sought to compare the portion of payment that accrued to physicians, facilities, and other providers, for both the colonoscopy and for all other episode procedures. We examine these portions in **Tables 8 and 9**:

Table 8. Colonoscopy Procedure – Portion of Payments Made to Facility vs. Physician

Setting of Colonoscopy	Episode Payments		
	Facility Payment to ASC	Facility Payment to Hospital	Physician Payment
Office	-	-	100%
Ambulatory Surgical Center	60%	-	40%
Outpatient Hospital	-	72%	28%

Table 9. Total Colonoscopy Episode – Portion of Payment Made to Facility vs. Physician

		Category of Outpatient Service					
Colonoscopy Setting	Payment Type	Procedures	Evaluation and Management	Tests	Imaging	Other	Total
Office	Facility Fees	3.2%	0.8%	1.1%	1.5%	0.2%	6.8%
	Professional Fees ¹	56.4%	10.3%	18.0%	6.3%	2.1%	93.2%
						Total	100%
Ambulatory Surgical Center	Facility Fees	33.0%	0.9%	1.4%	4.3%	0.5%	40.2%
	Professional Fees ¹	31.6%	7.3%	14.7%	4.4%	1.9%	59.9%
						Total	100%
Outpatient Hospital	Facility Fees	47.0%	1.6%	4.8%	6.5%	1.1%	61.1%
	Professional Fees ¹	22.6%	6.4%	5.2%	3.1%	1.6%	38.9%
						Total	100%

¹ Note: professional fees include fees paid to physicians in other settings other than that of the initial colonoscopy. Also includes payments to other types of outpatient providers, such as clinical laboratories.

A higher portion of total episode payments are received by facilities when colonoscopies are initially performed in the HOPD setting (61.1 percent), compared to colonoscopy episodes that originate in both the ASC (40.2 percent) and physician office (6.8 percent) settings.

There are several factors that contribute to these differences. First, Medicare uses different payment systems for different settings of care, reflecting differences in costs across settings. Second, facility fees for services in the HOPD and ASC settings are meant to cover the payments associated with operating the facilities. Higher-cost settings can incur higher fixed and variable costs, even if the procedure is similar across settings of care.

Third, utilization patterns may contribute to differences in payments for colonoscopy episodes across settings. These utilization patterns may be driven in part by differences in patient needs and acuity, as well as by practice patterns which may differ across settings of care (i.e., differences in utilization between hospital-based or non-hospital-based providers). Our risk adjustment methodology attempts to control for these differences.

And finally, hospitals may perform many of the services received during a typical colonoscopy episode in-house rather than outsourcing to a third-party provider. For example, a hospital may perform a greater share of lab tests using its own hospital-based laboratory instead of sending samples for testing to third party clinical laboratories. We did not examine the extent to which the hospital in/outsourcing was responsible for variation in cost across settings.

Evaluation and Management (E&M) Analysis

The purpose of exploring evaluation and management (E&M) services, which may be provided in an office, hospital outpatient department (HOPD), or in other settings, was to examine whether payments for other ambulatory services following an E&M visit differed depending on the setting of the visit.

a. Episode Generation Methodology

One of the challenges inherent in examining services following E&M visits is that patients receive E&M services for a wide variety of reasons, and therefore utilization following an E&M service may vary considerably depending on the purpose of the patient's visit and the chronic or acute condition for which they were seeing a physician.

To address this issue, we attempted to eliminate much of the inherent variation in reasons for receiving an E&M service by limiting our analysis to E&M services provided by a primary care practitioner in either the office or HOPD setting. Furthermore, because E&M service utilization may differ for patients recently discharged from a hospital, we created two "profiles" for our analysis.

- *Profile 1* includes all E&M services, for both new and existing patients, provided within 7 days following a hospitalization, provided by a primary care practitioner, in either the office or HOPD.
- *Profile 2* includes only new patient E&M services provided by a primary care practitioner, in either the office or HOPD. No constraint is imposed that a patient must have had a recent hospital stay.

For both profiles, once we identified the target E&M visit, we created episode windows that included all ambulatory services provided the day of and 7 days following the E&M visit. These 7-day windows constituted our "episodes" for the E&M analysis.

We defined "primary care practitioner" as the following Medicare specialties: General Practice, Family Practice, Internal Medicine, Geriatric Medicine, Nurse Practitioner, Physician Assistant, and Other/Unknown Specialty.

We conducted this analysis using a 5 percent sample of Medicare outpatient and carrier claims data. We pulled all claims meeting the above criteria and created the episodes in **Table 10** below:

Table 10. Evaluation and Management (E&M) Episode Counts

Profile and Setting ¹	Number of Episodes ²
Profile 1	116,724
Office	106,373

Hospital Outpatient	10,351
Profile 2	231,113
Office	211,984
Hospital Outpatient	19,129

¹ We excluded 2,115 HOPD E/M episodes from Profile 1 and 8,727 HOPD E/M episodes from Profile 2 where we were unable to find "matching" physician and HOPD claims for both the professional fee and hospital facility fee.

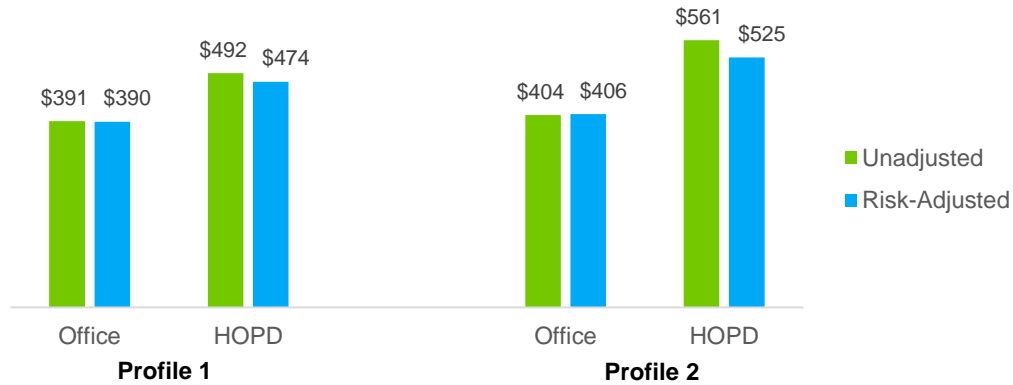
² For Profile 1, of the 106,373 office episodes, 71,578 (67 percent) were for patients with only one episode per year; for Profile 2, the counts were 211,984 and 159,881 (75 percent), respectively. For Profile 1, of the 10,351 HOPD episodes, 6,793 (66 percent) were for patients with only one episode per year; for Profile 2, the counts were 19,129 and 14,413 (75 percent), respectively.

We stratified the E&M visits by acute vs. chronic to better determine the reason behind the E&M visit. To accomplish this, we examined the primary ICD-9-CM diagnosis codes associated with the E&M visit and categorized each visit into clinically meaningful categories using the Agency for Healthcare Research & Quality (AHRQ) Clinical Classifications Software (CCS) for ICD-9-CM. We then further categorized each as acute or chronic by using CMS' Chronic Conditions Data Warehouse. Recognizing that differences in patient demographics, conditions, and other variables can contribute to differences in utilization and payments across settings of care, we developed a risk adjustment model as part of this analysis to account for certain patient characteristics and differences in practice patterns across settings. As for all three types of procedure episodes, we also excluded outlier episodes (the top 0.5 percent of episodes based on total episode payment) because of poor performance of risk adjustment models for these episodes. For purposes of risk adjustment, we also flagged whether a patient had a readmission or emergency department visit within the 7 days following the E&M service. Additional information about the risk adjustment methodology is detailed in the risk adjustment methodology section of this paper.

b. Results

Below are the results of our E&M analyses for both Profile 1 and Profile 2, comparing average ambulatory payments for 7 days following an E&M visit in the HOPD vs. office setting:

Figure 3. Average 7 Day Episode Payments for E&M Profiles 1 and 2



Notes: 95% confidence intervals of estimated average unadjusted and risk adjusted payments not shown in Figure 3. Excludes top 0.5% of outliers.

We find that for Profile 1, E&M services in the HOPD are associated with higher total ambulatory payments across episodes following the E&M visit. On average, episode payments for Profile 1 are \$84 (22 percent) higher after adjusting for risk factors. We find similar results for Profile 2. On average, episode payments for Profile 2 are \$119 (29 percent) higher after adjusting for risk factors. Additional detail on these findings can be found in **Tables 11 and 12** below:

Table 11. Profile 1 – E&M Services by a Primary Care Practitioner Following a Planned Hospitalization

E&M Setting	E&M Visit Only (Unadjusted)			Total 7-Day Episode Payment	
	E&M Prof. Fee	E/M Facility Fee	Total Payment for E/M Service	Unadjusted	Risk-Adjusted
Office	\$88 (\$87, \$89)	\$0	\$88 (\$87, \$89)	\$391 (\$386, \$396)	\$390 (\$386, \$394)
Outpatient Hospital	\$64 (\$63, \$65)	\$88 (\$87, \$89)	\$152 (\$150, \$154)	\$492 (\$474, \$510)	\$474 (\$461, \$487)
Difference Relative to Office	-\$24 (-\$25, -\$23)	+\$88 (+\$87, +\$89)	+\$64 (+\$62, +\$65)	+\$101 (+\$82, +\$120)	+\$84 (+\$71, +\$98)

Notes: 95% confidence intervals of estimated average unadjusted and risk adjusted payments shown in parentheses. Excludes top 0.5% of outliers based on total episode spending.

Table 12. Profile 2 – New Patient E&M Services by a Primary Care Practitioner

E&M Setting	E&M Visit Only (Unadjusted)			Total 7-Day Episode Payment	
	E&M Prof. Fee	E/M Facility Fee	Total Payment for E/M Service	Unadjusted	Risk-Adjusted
Office	\$115 (\$114, \$116)	\$0	\$115 (\$114, \$116)	\$404 (\$401, \$407)	\$406 (\$404, \$408)
Outpatient Hospital	\$86 (\$85, \$87)	\$96 (\$95, \$97)	\$182 (\$181, \$184)	\$561 (\$547, \$576)	\$525 (\$515, \$535)
Difference Relative to Office	-\$28 (-\$29, -\$27)	+\$96 (\$95, \$97)	+\$67 (\$66, \$69)	+\$157 (+\$142, +\$172)	+\$119 (+\$109, +\$130)

Note: 95% confidence intervals of estimated average unadjusted and risk adjusted payments shown in parentheses. Excludes top 0.5% of outliers based on total episode spending.

Average unadjusted payments for the E&M service itself are also higher in the HOPD setting compared to the office setting (73 percent higher for Profile 1 and 58 percent higher for Profile 2). This finding was expected, as payment rates for E&M services set by the Centers for Medicare & Medicaid Services (CMS) for both the physician facility payment are greater in the HOPD setting than in the office setting.

In stratifying E&M visits by acute vs. chronic, we find that total episode payments for both Profiles are slightly higher for acute conditions than for chronic conditions, as shown in **Table 13** below:

Table 13. Stratification of E&M Episodes by Reason for E&M Visit (Acute vs. Chronic)

	Profile 1: E&M Services by a Primary Care Specialty Following a Planned Hospitalization		Profile 2: New Patient E&M Services Performed by a Primary Care Specialty	
	Office	Outpatient Hospital	Office	Outpatient Hospital
Acute	\$405 (\$399, \$410)	\$503 (\$485, \$521)	\$408 (\$406, \$412)	\$535 (\$523, \$547)
Chronic	\$371 (\$365, \$376)	\$438 (\$419, \$456)	\$400 (\$396, \$404)	\$505 (\$487, \$523)

Notes: 95% confidence intervals of estimated average unadjusted and risk adjusted payments shown in parentheses. Excludes top 0.5% of outliers based on total episode spending.

c. Discussion

Our analysis of E&M visits finds that HOPD-based E&M visits are associated with higher payments over a 7 day period following the E&M service.

There may be several factors driving these differences in payments. Hospital-based physicians may be more likely to refer patients to other providers within the same hospital, whereas physicians who practice in freestanding offices may be more likely to refer to other physicians in the community.

Some of the difference may also be due to differences in patient severity. A patient may decide to visit a HOPD because of more severe symptoms or may continue to receive services at more intensive settings because of a more severe diagnosis. However, we did attempt to account for differences in patient demographics and severity through our risk adjustment models.

For Profile 1, the average difference in E&M episode payment is \$101 on an unadjusted basis and \$84 after risk adjustment, meaning \$17 (or 17 percent) of the difference between HOPD and office E&M episode payments can be accounted for by factors included in our risk adjustment model. For Profile 2, the average difference in E&M episode payment is \$157 on an unadjusted basis and \$119 after risk adjustment, meaning \$38 (or 24 percent) of the difference between HOPD and office E&M episode payments can be accounted for by factors included in our risk adjustment model.

The remaining variation in payments across settings may be due to several factors, including differences in reimbursement rates for services in the office compared to the HOPD, patient factors not accounted for in our risk adjustment model, and unrelated services received by beneficiaries during the episode window. More specifically, while we examined diagnoses across the initial E&M visits, we did not examine diagnoses for all follow-up ambulatory visits. As a result, some of the ambulatory services received by patients in the 7 days following the E&M visit may be unrelated to the condition for which the patient received the E&M service.

CONCLUSION

Our data analyses confirm and more fully expand on the conclusions of several previous studies that found Medicare payments to be higher in the hospital outpatient department (HOPD) than in the ASC or physician office settings. To more fully capture the impact of this payment differential, our findings also extend to episodes of care around the procedures themselves. This is the first time such an analysis has been done. These results show that there are further differences in the total cost of care across settings when additional services adjacent to the primary service are also considered.

These findings hold even after applying a risk adjustment methodology to control for differences in patient demographics and patient severity across settings, as patients tend to be sicker in the HOPD setting compared to the office or ASC settings, and can drive

differences in payments. Controlling for the risk-adjustment factors discussed in Appendix IV.2 explains between 1 percent (3-day cardiac imaging episode) and 27 percent (60-day colonoscopy) of total episode payment when comparing office based and HOPD-based procedures. The remaining, unexplained variation is likely due to differences across settings in reimbursement rates, utilization of services, or by variables not accounted for in our risk-adjustment model.

These findings show that higher payments for these procedures in the HOPD setting tend also to be followed by higher payments on other services for the same beneficiaries during the episode. These findings remain true even after adjusting for risk factors such as age, gender, CMS Hierarchical Condition Categories (CMS-HCCs), and other factors described in Appendix VI.2.

It is possible that there are other contributing factors to the higher payments for HOPD-delivered services apart from those considered in our risk adjustment analysis. However, it appears clear that higher payments are due to a significant extent to higher reimbursement rates for the original procedures themselves, higher reimbursement rates for associated ambulatory services performed in the HOPD setting, and higher rates of utilization of services in other settings (e.g., the inpatient setting) for cardiac imaging and colonoscopy analyses.

This analysis raises numerous questions and issues of interest to executive and legislative policymakers interested in neutralizing site of service payment incentives, as well as stakeholders who are interested in whether and how different patient populations drive spending across settings of care. Overall, this analysis demonstrates that there are implications for spending over time and across settings when care is initiated in the higher-paying HOPD setting – specifically, that payment differentials that begin with an initial HOPD service may extend and amplify throughout the entire episode, even when controlling for patient demographics and severity.

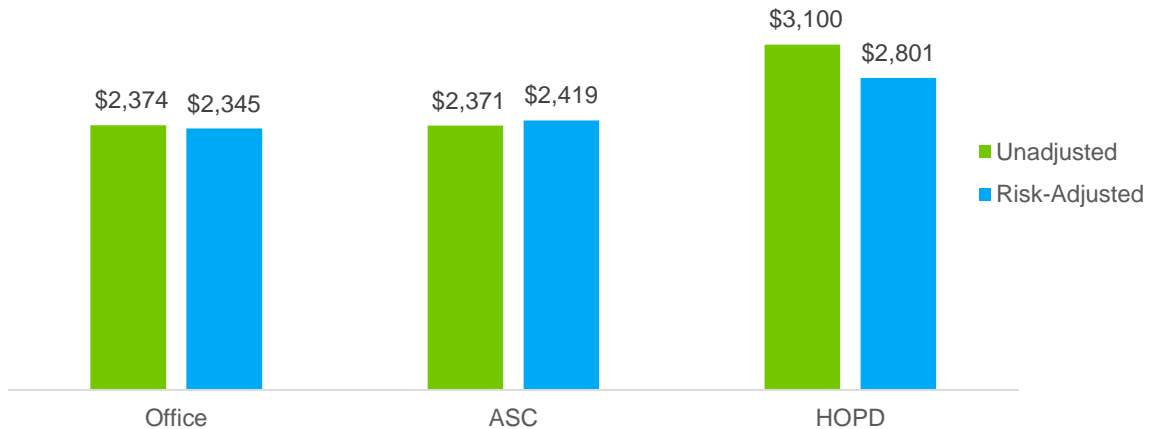
APPENDIX

Summary of Results from the 61-day Colonoscopy Episode Analysis

In addition to the 22-day colonoscopy episode presented in Section IV.2, we also examined a longer episode of time around the Target colonoscopy, specifically a 61-day episode consisting of the day of the colonoscopy and 30-days before and 30-days after the colonoscopy.

Below are the high-level results of our analyses, comparing average payments for a 61-day colonoscopy episode in the physician office, ASC, and HOPD settings:

Figure 4. Average Payment Per 61-Day Colonoscopy Episodes



Note: 95% confidence intervals of estimated average unadjusted and risk adjusted payments not shown in Figure 4.

Table 14. Average Payment for 61-Day Colonoscopy Episodes

Colonoscopy Setting	Unadjusted: All Episodes	Unadjusted: Top 0.5% Outliers Removed	Unadjusted Payment Relative to Office	Risk-Adjusted: Top 0.5% Outliers Removed	Risk-Adjusted Payment Relative to Office
Office	\$2,374 (\$2,258, \$2,490)	\$2,282 (\$2,195, \$2,369)	\$0	\$2,345 (\$2,284, \$2,406)	\$0
ASC	\$2,371 (\$2,339, \$2,405)	\$2,300 (\$2,275, \$2,326)	+\$18 (-\$73, +\$109)	\$2,419 (\$2,399, \$2,439)	+\$74 (+\$11, +\$137)
HOPD	\$3,100	\$2,908	+\$626	\$2,801	+\$456

(\$3,058, \$3,143)	(\$2,879, \$2,937)	(+\$534, +\$718)	(\$2,782, \$2,821)	(+\$392, +\$520)
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The unadjusted difference between the Office and the HOPD for a 61-day colonoscopy episode is \$626. After applying our risk adjustment methodology, the difference between the Office and the HOPD drops to \$456. The difference between these differences (\$170, or 27 percent) is the portion of the payment differential between settings that can be explained by the factors included in our risk adjustment models.

Risk Adjustment Methodology

a. Purpose and General Approach

We applied a risk adjustment methodology to each of the three areas of analyses to determine and control for the portion of payment variance across settings attributable to common demographic factors and clinical conditions. We applied a similar risk adjustment methodology to each of the three areas, with slight differences in model features depending on the analysis.

Our general approach to risk adjustment is based, in part, on a standard methodology used by The Centers for Medicare & Medicaid Services (CMS) to estimate, and predict, spending patterns for Medicare Advantage (MA) plan members. Specifically, we created indicators for each Hierarchical Condition Category (HCC) from Version 12⁷¹ of the CMS-HCC grouper (the version of the CMS-HCC model in effect at the time of the utilization experience we analyzed. We identified these conditions based on two time windows (90 days and 365 days) anchored at the later endpoint by the episode procedure date. The 365-days window is the standard time period for measuring HCCs in the CMS-HCC model for identifying pre-existing chronic and acute conditions in the past year. We also included HCCs based on the shorter timeframe to identify any new conditions that may have arisen prior to the procedure and may have influenced the need for the procedure and other proximal services. We also included patient demographics, select other service use during the episode. We stratified models by type of procedure (e.g., screening versus diagnostic colonoscopy) to account for differences in the effect of each risk adjustment factor across the procedure strata.

We supplemented this approach by researching and including additional risk factors that may drive differences in episodic payments for each of the three conditions. We used a common set of factors identifying comorbid conditions because the purpose of including these was to generally adjust for their effects on patients' spending and utilization, not to craft parsimonious models specific to each condition (and which might change if using data

⁷¹ 2012 Model Software/ICD-9-CM Mappings. Centers for Medicare & Medicaid Services. 2012 <
<https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/2012MidyearFinalModel.zip>

from a different year). However, we did select an additional small set of procedure-specific adjusters that were also meaningful from a clinical perspective.

After estimating a variety of risk adjustment models, we chose those with the best predictive performance. We also excluded outlier episodes (the top 0.5 percent of episodes based on total episode payment) because of poor predictive performance of Hierarchical Condition Categories (CMS-HCCs) for these episodes.

Methodology

a. Episode Creation

We conducted a brief review of literature around practice patterns for each area of analysis to determine the length of each episode. Our approach to episode length was to choose appropriate episode lengths, but also to create broader episode windows to examine whether differences in episodes hold true for longer episodes with greater variation in utilization of services.

For each of the three areas of analysis, we developed different definitions of an episode, based on both length of the episode and the criteria that trigger the start of an episode. Generally, our episode definitions reflect our judgement about the appropriate length and criteria, depending on the analysis. For example, the colonoscopy episode definition is based on prior research in the area, while the definition for evaluation and management (E&M) reflects the tradeoff between ensuring the comparisons across settings are as consistent as possible and ensuring the episode captures variation in payments and utilization related to the original reason for the E&M visit. In both the colonoscopy and cardiac imaging analyses, we examined and present findings for both wide and narrow time windows for our episodes.

We excluded certain patients from our analyses, including patients who died during the year of analysis (2012) and those with end-stage renal disease (ESRD). Additional patients were excluded for the colonoscopy analysis, and are described in the colonoscopy section of this paper.

We then built each episode using a 5 percent sample of the 2012 Medicare Standard Analytical File (SAF) for Part B services (institutional and professional services), and 100 percent of 2012 Medicare claims for inpatient, skilled nursing, home health, hospice, and durable medical equipment.

The colonoscopy risk adjustment models include a stratification of colonoscopy episodes by type of colonoscopy (screening vs. diagnostic) and whether the colonoscopy included separately-billed anesthesia. These factors allow us to determine differences in types of colonoscopies and practice patterns across settings of care, which in turn lead to differences in episode costs.

For the E&M risk adjustment model, we stratified the E&M visit episodes by whether the beneficiary was being seen for an acute condition or a chronic condition. This differentiation allows the risk adjustment models to better capture the differences in spending patterns. To establish whether an E&M visit was chronic or acute, we used the Agency for Healthcare Research & Quality (AHRQ) Clinical Classifications Software (CCS)⁷² for ICD-9-CM, which classifies ICD-9-CM codes into clinically meaningful categories. We then determined whether each clinical classification was either acute or chronic, by crosswalking each condition to the 27 chronic conditions in CMS' Chronic Conditions Data Warehouse⁷³.

b. Determining Risk Factors

We also examined which additional factors to include in our risk adjustment models, beyond demographics, disability, and comorbid conditions, may drive differences in payment across various types of episodes. We included these variables in each of our risk adjustment models, with certain features applicable only to certain analyses. A list of these factors is included in **Table 15** below.

Table 15. Risk adjustment Factors Used in Final Models

Risk adjustment Factors	Included in Model
Age	All Models
Gender	All Models
Original Reason for Medicare Entitlement (Old Age/Disability)	All Models
Current Reason for Medicare Entitlement (Old Age/Disability)	All Models
Medicaid Status	All Models
CMS Hierarchical Condition Categories (CMS-HCCs)	All Models
Procedure Line Item Diagnosis ⁷⁴	Evaluation & Management
Readmission During Episode	All Models
ED Visit During Episode	All Models
Use of Separately-Billed Anesthesia During the Colonoscopy	Colonoscopy
Stratification: Colonoscopy Type (Diagnostic vs. Screening)	Colonoscopy

⁷² HCUP CCS. Healthcare Cost and Utilization Project (HCUP). June 2015. Agency for Healthcare Research and Quality, Rockville, MD. [Link](#).

⁷³ Chronic Conditions Data Warehouse. Centers for Medicare & Medicaid Services. 2015. [Link](#).

⁷⁴ Diagnoses were assigned to AHRQ Clinical Classification Software (CCS) single-level categories and then grouped further into broader, clinically coherent categories. HCUP CCS. Healthcare Cost and Utilization Project (HCUP). June 2015. Agency for Healthcare Research and Quality, Rockville, MD. [Link](#).

Stratification: Type of imaging (without probe; with esophageal probe; vs. other ultrasound)	Cardiac Imaging
Stratification: Clinical Reason for E&M Visit (Chronic vs. Acute Condition)	Evaluation & Management

c. Condition-specific models

We used CMS-HCCs to determine individual disease groups for beneficiaries in our sample. Examples of common CMS-HCC conditions in our patient sample were diabetes, heart conditions, COPD, and vascular disorders. In each condition model, we used various look-back periods to estimate the HCCs. For example, for colonoscopy and cardiac imaging, we used two sets of HCCs—one based on the prior 365 days of medical claims and the second was based on the most recent 90 days of medical claims. For E&M visits, we used the HCCs based solely on the most recent 90 days of medical claims. The purpose for including these varying time periods is to account for medical conditions that occurred adjacent to the particular procedure, with the assumption that events or conditions that occur within 90 days of a procedure will be more likely to impact the spending and utilization patterns of an adjacent episode. We limited the E&M visit look-back period to 90 days (without using a 365 day period) since the unit of analysis (one E&M visit) is small and much less likely to be impacted by an event or condition that occurred beyond 90 days from the visit.

Medicaid status was determined using a claims indicator for each month during 2012 as to whether the beneficiary’s state Medicaid program paid for Medicare’s Part B monthly premiums. This indicator served to determine whether a Medicare beneficiary was also Medicaid eligible during the year of analysis.

d. Predictive Performance

Using the risk adjustment factors described above, we developed and tested two risk adjustment models for each of the three analyses: Ordinary Least Squares (OLS) and a Generalized Linear Model (GLM). We chose the models with the best out-of-sample predictive power (overall R^2 and ratios of predicted to actual values across deciles of actual and predicted values) for each area of analysis. After selecting the type of statistical model, we re-estimated the model on the full sample. The overall predictive power (R^2) of each model in the full sample for each area of analysis is shown below in **Table 16**.

Table 16. Model Performance Across Areas of Analysis

Analysis	Episode Length	Model Explanatory Power (R^2)
Cardiac Imaging	2-Day	0.150
Cardiac Imaging	21-Day	0.429
Colonoscopy	21-day	0.331
Colonoscopy	60-day	0.496
E&M Profile 1	7-day	0.032
E&M Profile 2	7-day	0.059

The risk adjustment models exhibit a great deal of variation across areas of analysis in their overall R^2 , from as low as 3 percent for E&M Profile 1 to nearly 50 percent for 60-day colonoscopy episodes. In attempting to explain some of the variation in differences in payments across care settings, we accounted for common demographic and clinical patient characteristics. Only a portion of the variation in payments across settings can be explained by these models, with the remaining variation due either to differences in reimbursement for the services and other procedures within the episode and/or by other risk adjustment factors not included in our model. In particular, the relatively low explanatory power for the E&M episode risk adjustment models is likely driven by the fact that there are very many reasons why a person may visit a physician, but that medical condition coded in diagnosis codes are only one dimension of why patients have these visits.

Separate from the explanatory power of the risk adjustment models is the issue of the degree to which differences in risk factors can explain (based on the risk adjustment model) average cost differences between settings. The percentage of the cost difference between physician office and HOPD settings that remains after risk adjustment is shown in **Table 17** below. The greater is this percentage, the greater the amount of the cost difference that may be due to the setting of the index visit. For example, for cardiac imaging 2-day episodes, virtually none (100 percent minus 99 percent, or one percent) of the cost difference between office and HOPD settings for the index procedure visit is driven by differences in risk factors. Even for cardiac imaging 21-day episodes, only 13 percent (100 percent minus 87 percent) of the office versus HOPD difference in payment is driven by differences in risk factors.

Table 17. Variation in HOPD vs. Office Episode Payment that Can Be Explained by Risk Adjustment

Analysis	Episode Length	Difference Between Hospital Outpatient and Office Episode Payment Explained by Differences in Risk Factors Risk Adjustment*
Cardiac Imaging	3-day	1%
Cardiac Imaging	22-day	13%
Colonoscopy	22-day	9%
Colonoscopy	61-day	27%
E&M Profile 1	7-day	17%
E&M Profile 2	7-day	24%

* Note: this column refers to the payment in a hospital setting above that in the office setting, and compares the unadjusted difference with the adjusted difference to show what portion of variation in episode payment can be explained by our risk adjustment models

Limitations and Other Notes

There are a number of potential limitations of this study. First, the risk factors are derived from administrative billing data. As mentioned earlier, particularly for E&M services, it is possible that there are factors not identified in billing data that drive whether a person sees a physician or is treated in the hospital outpatient (HOPD) setting. Furthermore, these factors could play a role in determining what additional services a beneficiary may need within seven days of an E&M visit. Second, although for each type of service we defined two episode definitions, the true data generating model for payment and spending may be much more complex (e.g., condition-specific optimal episode lengths), and so our analysis may not consider all effects of setting on total episode payment. Finally, we focused our analysis on three specific groups of physician services among the multitude that are performed in both settings. As a result, our findings may not be representative of the differences in payment across settings for other services. However, the three procedures we chose, cardiac imaging, colonoscopies, and E&M services, are all common Medicare procedures.

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