



Primary Care Options in Rural Healthcare

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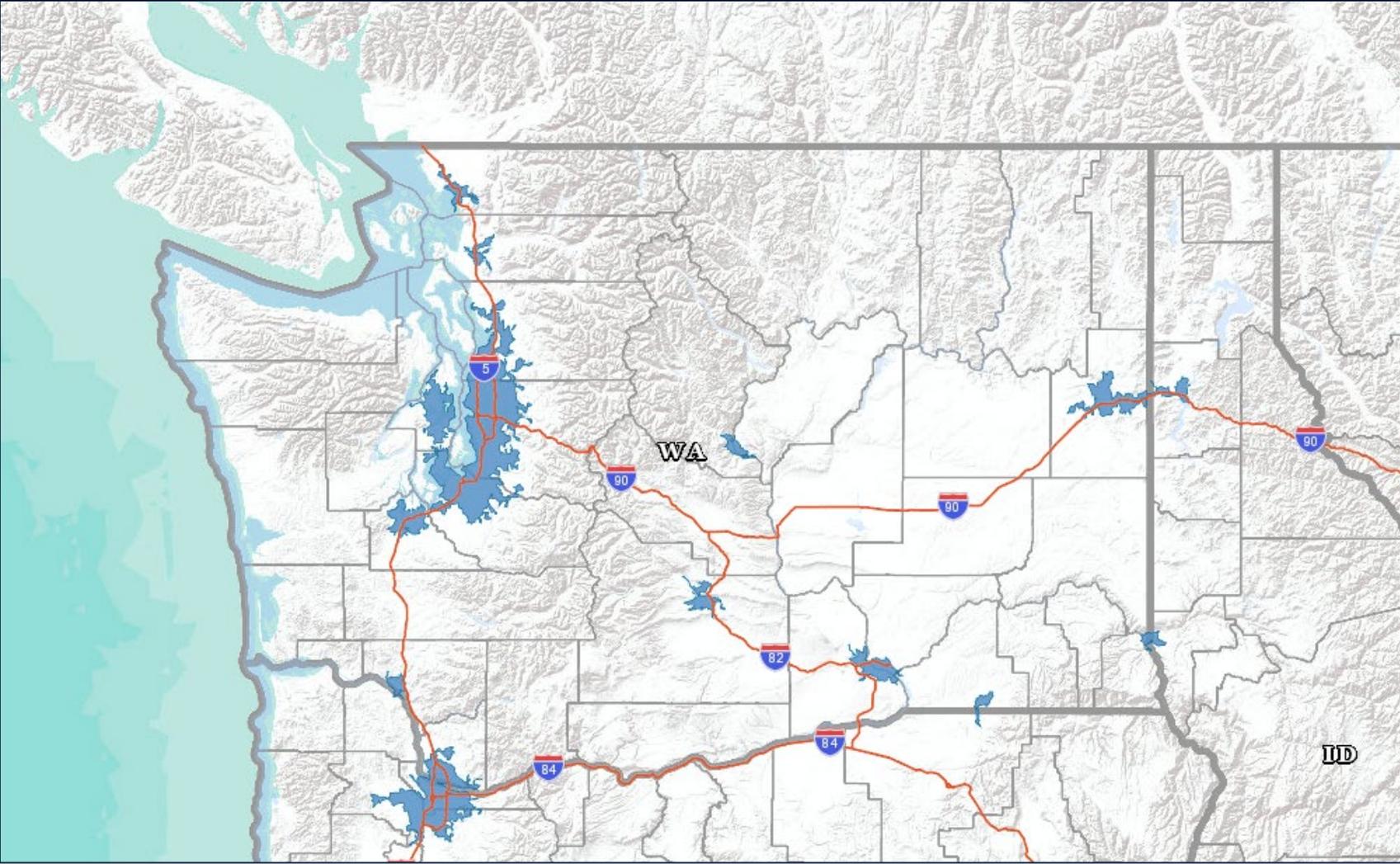
- With uncertainty around several significant provisions, such as payment, insurance, and delivery-system reforms, the healthcare industry must address future market changes
- An effective hospital primary care strategy is an essential component to address those market changes; especially in rural healthcare
 - The patients served, clinic location, and provider productivity must all be considered when developing a primary care strategy
- Since the hospital and clinic designation type can impact reimbursements and other opportunities received by the clinic, hospitals should evaluate each of the following clinic designation types to ensure an appropriate strategy:
 - Federally Qualified Healthcare Center (FQHC)
 - Provider-Based Clinic (PBC)
 - Rural Health Clinic (RHC)
 - Includes Provider-Based Rural Health Clinic (PB-RHC)
 - Free-Standing Health Clinic (FSHC)

DEFINITIONS / REGULATIONS

- Some clinic designation types require the clinic to provide services to a specific group of patients and or operate in a certain location such as the following:
 - **Rural Area Location**
 - The federal government uses both the U.S. Census Bureau and the Office of Management and Budget (OMB) to determine “rural” areas
 - The Census Bureau does not actually define “rural”; however, rural encompasses all population, housing, and territory not included within an urbanized area
 - The Census Bureau defines urban as the following:
 - Urbanized Areas (UAs) of 50,000 or more people
 - Urban Clusters (UCs) of at least 2,500 and less than 50,000 people
 - OMB defines urban areas as the following:
 - Metropolitan contains an urban area of 50,000 or more population
 - OMB considers all counties that are not part of a metropolitan area as rural

Rural and Shortage Area Designations

- Rural Area Designations

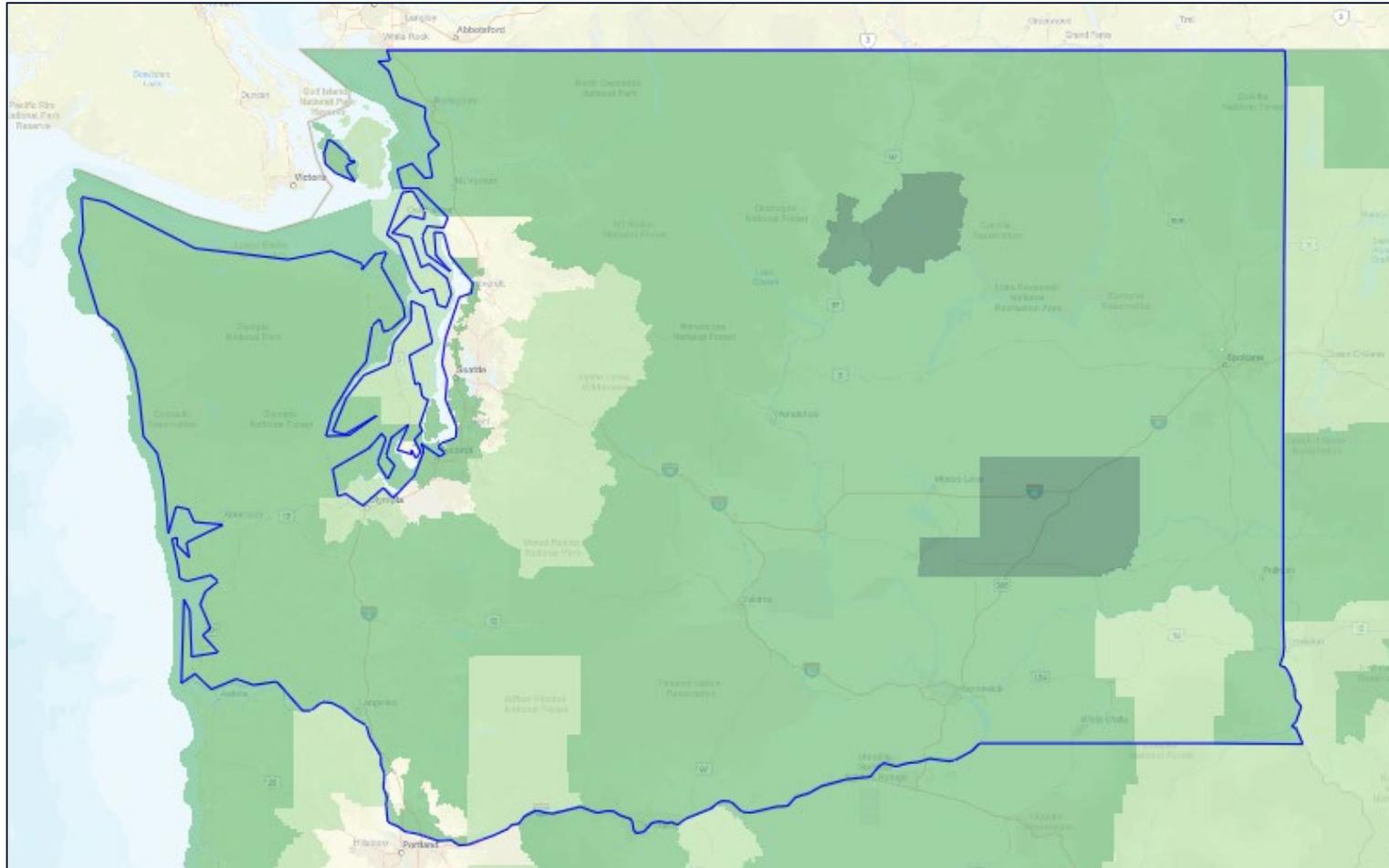


- **Health Professional Shortage Area (HPSA)**

- Health Professional Shortage Areas (HPSAs) are designated by HRSA as having shortages of primary care, dental care, and/or mental health providers within a specific geographic area, population, or facility
 - Geographic HPSA
 - A shortage of providers for an entire group of people within a defined geographic area
 - The formula used to designate primary care HPSAs does not take into account the availability of additional primary care services provided by Nurse Practitioners and Physician Assistants in the area
 - Population HPSA
 - A shortage of providers for a specific group of people within a defined geographic area (e.g. low-income, migrant farm workers)
 - Facility HPSA
 - HRSA automatically applies a facility HPSA to the following:
 - Federally Qualified Health Center (FQHC)
 - FQHC Look-A-Likes
 - Indian Health Facilities
 - IHS and Tribal Hospitals
 - Dual-funded Community Health Centers/Tribal Clinics
 - CMS-Certified Rural Health Clinics (RHC)

Rural and Shortage Area Designations

- Health Professional Shortage Area (HPSA)
 - Primary Care



- **Medically Underserved Area (MUA)**

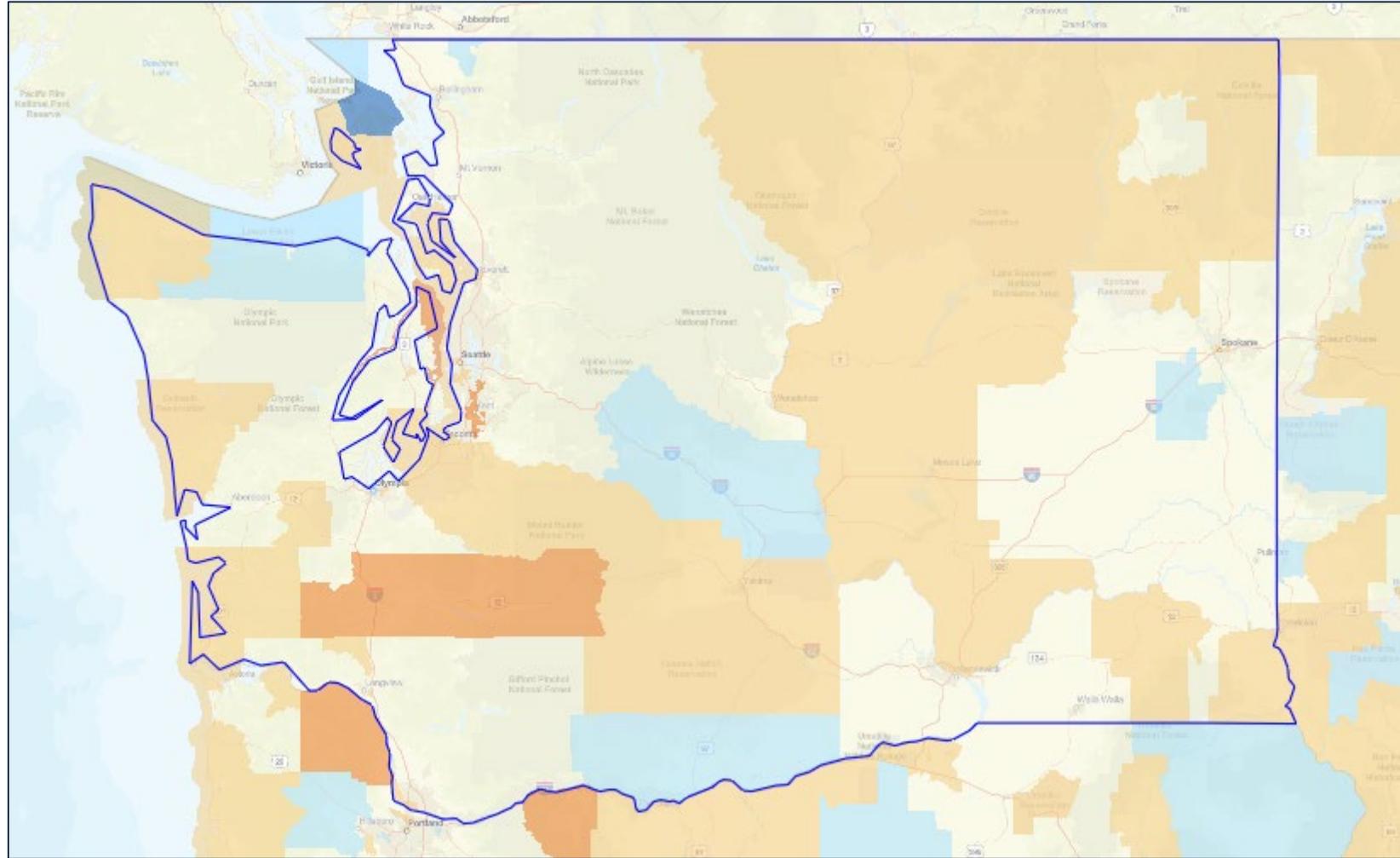
- MUAs have a shortage of primary care health services within a geographic area such as:
 - a whole county;
 - a group of neighboring counties;
 - a group of urban census tracts; or
 - a group of county or civil divisions
- To qualify as an MUA, the clinic must operate in an area with an Index of Medical Underservice (IMU) rating of 62.0 or less on a scale from 0 to 100
 - Public Law 99-280 states that a population group that does not have an IMU less than 62.0 can still obtain designation if “unusual local conditions exist which are a barrier to access to or the availability of personal health services”

- **Medically Underserved Population (MUP)**

- MUPs are specific sub-groups of people living in a defined geographic area with a shortage of primary care services
- These groups may face economic, cultural, or linguistic barriers to health care and include, but are not limited to, those who are:
 - Homeless, Low-Income, Medicaid-eligible, Native American; or Migrant Farmworkers
 - Index of Medically Underserved (IMU) can range from 0 to 100, where zero represents the completely underserved
 - Areas or populations with IMUs of 62.0 or less qualify for designation as an MUA/P

Rural and Shortage Area Designations

- **Medically Underserved Area (MUA)**



- **Governor-Designated Secretary-Certified Shortage Areas**
 - Governors may designate areas of their state as shortage areas specifically for the purpose of Rural Health Clinic (RHC) certification. These areas must meet specific criteria
 - State-created and HRSA-certified plans outline how to identify areas that need RHC services, but do not otherwise qualify for HPSA or MUA/P designation
 - States wishing to acquire a Governor's Designated Shortage Area for an RHC must submit:
 - A signed letter from the governor requesting the designation; and,
 - A state-specific Shortage Area Plan detailing, at minimum state's rational service area criteria and component guidelines for HRSA's approval
 - Washington does not currently have any current Governor-Designated Secretary-Certified Shortage Areas

- The Washington State Office of Community Health Systems (WSOCHS) serves as the State Office of Rural Health (SORH) and helps healthcare facilities in several ways
 - WSOCHS provides technical assistance to rural health clinics, critical access hospitals, and community health centers along with other health facilities located in Washington's rural areas
- WSOCHS can assist and plays a critical role in the ability of hospitals to qualify for certain designations and in the following areas:
 - HPSA Designation and Renewal
 - RHC Rate Establishment
 - Rural Designation
 - Application Assistance
 - CAH Distance Analysis
 - Provider-Based Requirements

Practice Designation Types

- Each of the four clinic types encompass different reimbursement methodologies that can greatly impact reimbursements received from Medicare and Medicaid
 - To qualify for a designation type may require the practice, or entity that owns the practices, to meet certain conditions
 - The table below highlights those differences:

Reimbursement Options	FQHC	PBC		RHC	FSHC
		CAH	PPS		
330 Grant	Yes	No	No	No	No
340B Pharmacy	Yes	Yes	Yes*	Yes*	No
Enhanced Technical Charge	No	Yes	No	Yes	No
Method II Billing	No	Yes	No	No	No
Tort Reform - Malpractice Savings	Yes	No	No	No	No
Enhanced PPS Reimbursement	Yes	Yes	No	Yes	No

* If owned and operated by a hospital that qualifies (For non-CAHs, the hospital must meet the required DSH % to qualify for 340B)

New RHC Reimbursement Methodology

- On December 27, 2020, the President signed into law, the “*Consolidated Appropriations Act, 2021 (CAA)*” which changed the reimbursement methodology for Rural Health Clinics (RHC) starting on April 1, 2021
 - Starting on April 1, 2021, all new RHCs established after December 31, 2019 (*December 31, 2020 after H.R. 1868*), regardless of whether they are independent, owned and operated by a hospital with fewer than 50 beds, or owned and operated by a hospital with greater than 50 beds, shall be reimbursed based on reasonable cost with an upper payment limit (UPL) set at the following rates:
 - a) In 2021, after March 31, at \$100 per visit;
 - b) In 2022, at \$113 per visit;
 - c) In 2023, at \$126 per visit;
 - d) In 2024, at \$139 per visit;
 - e) In 2025, at \$152 per visit;
 - f) In 2026, at \$165 per visit;
 - g) In 2027, at \$178 per visit;
 - h) In 2028, at \$190 per visit;
 - i) In subsequent years, the rate will increase based on the Medicare Economic Index (MEI) for primary care services
 - RHCs owned and operated by a hospital with fewer than 50 beds and established on or before December 31, 2019, will use their 2020 rate to establish a clinic-specific grandfathered UPL that will then be increased each year based on the MEI
- Since the final legislation varied greatly from the RHC Modernization Act and due to the impact on provider-based RHCs (PB-RHC), efforts are underway to change certain provisions
 - On April 14, 2021, the President signed H.R. 1868 into law which fixed some of the grandfathering issues caused through the change of the RHC reimbursement methodology in the Consolidated Appropriations Act, 2021

RHC Specific Impact - Grandfathered

- With a change in the reimbursement methodology, hospitals must evaluate and understand the net impact on future reimbursements

- Critical Access Hospital (Former Un-Capped RHC Rate):

- The following table presents the net impact on reimbursements for a CAH that operates 2 RHCs if the law went into effect in 2016 and the practices were “grandfathered”:

	2016	2017	2018	2019	COMBINED	Rate Increase
Cost-Based Rate	\$ 154.85	\$ 188.94	\$ 223.91	\$ 220.92		43%
Grandfathered UPL	154.85	157.01	159.21	161.44		4%
Variance	\$ -	\$ (31.93)	\$ (64.69)	\$ (59.48)	\$ (39.85)	<-- AVG
Medicare Visits	4,114	4,226	4,269	4,653	17,262	
Lost Reimbursement	\$ -	\$ (134,927)	\$ (276,183)	\$ (276,757)	\$ (687,867)	

- Hospital-based RHC with > 50 Beds (Former Capped RHC Rate):

- The following table presents the net impact on reimbursements for 2 hospital-based RHCs if the law went into effect in 2016:

	2016	2017	2018	2019	COMBINED	Rate Increase
Clinic Cost / Visit	\$ 145.56	\$ 126.50	\$ 131.06	\$ 141.35		-3%
Independent Rate	81.32	82.30	83.45	84.70		4%
New UPL RHC Rate	100.00	113.00	126.00	139.00		39%
Variance	\$ 18.68	\$ 30.70	\$ 42.55	\$ 54.30	\$ 35.80	<-- AVG
Medicare Visits	2,478	2,319	2,379	2,065	9,241	
Reimbursement Gain	\$ 46,289	\$ 71,193	\$ 101,226	\$ 112,130	\$ 330,838	

- Stroudwater assumed an annual Medicare Economic Index (MEI) increase of 1.4% for both scenarios
- Since RHCs will receive the lesser of their cost-based rate or the UPL, the green-shaded box highlights whether the practice would receive their cost-based rate or the UPL

RHC Specific Impact - New RHC

- Critical Access Hospital (Former Un-Capped RHC Rate):

- The following table presents the net difference in reimbursements received if the CAH established the same 2 practices as new RHCs in 2016; however, the practices were subject to the new UPL:

	2016	2017	2018	2019	COMBINED	Rate Increase
Cost-Based Rate	\$ 154.85	\$ 188.94	\$ 223.91	\$ 220.92		43%
New RHC UPL Rate	100.00	113.00	126.00	139.00		39%
Variance	\$ (54.85)	\$ (75.94)	\$ (97.91)	\$ (81.92)	\$ (77.96)	<-- AVG
Medicare Visits	4,114	4,226	4,269	4,653	17,262	
Lost Reimbursement	\$ (225,640)	\$ (320,933)	\$ (417,968)	\$ (381,178)	\$ (1,345,719)	

- Hospital-based RHC with > 50 Beds (Former Capped RHC Rate):

- The following table presents the net difference in reimbursements received if the hospital-based RHCs were established as new RHCs and subject to the new UPL:

	2016	2017	2018	2019	COMBINED	Rate Increase
Clinic Cost / Visit	\$ 145.56	\$ 126.50	\$ 131.06	\$ 141.35		-3%
Independent Rate	81.32	82.30	83.45	84.70		4%
New UPL RHC Rate	100.00	113.00	126.00	139.00		39%
Variance	\$ 18.68	\$ 30.70	\$ 42.55	\$ 54.30	\$ 35.80	<-- AVG
Medicare Visits	2,478	2,319	2,379	2,065	9,241	
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- Stroudwater assumed an annual Medicare Economic Index (MEI) increase of 1.4% for both scenarios
- Since RHCs will receive the lesser of their cost-based rate or the UPL, the green-shaded box highlights whether the practice would receive their cost-based rate or the UPL

STRATEGIC OPTIONS

- With declining reimbursements, all systems need to leverage available reimbursement opportunities to improve financial performance
- The following opportunities are available to hospitals and systems to improve reimbursements when those practices can meet certain eligibility requirements:
 1. Convert eligible practices within a health system or at a hospital to a designation that provides the most advantageous reimbursement opportunity
 2. Realign practices within a health system to leverage reimbursement advantages and additional revenue available to the system
 3. Integrate specialty practices, when possible, within a PB-RHCs under a hospital of less than 50 beds that has a grandfathered PB-RHC reimbursement rate
 4. Acquire independent practices to leverage provider-based reimbursement opportunities and other additional revenue streams available to hospitals
 - This opportunity may not lead to a net positive return; however, will increase in functional, contractual, and governance alignment and increase the attributed lives associated with the hospital / health system

CASE STUDIES

Opportunity 1: Multi-hospital System (NY)

- A five-hospital system with more than 1,000 physicians and other clinicians
 - Hospitals include:
 - A 400-bed, short-term acute facility
 - A 320-bed, short-term acute facility
 - A 60-bed, short-term acute facility
 - A 25-bed Critical Access Hospital (CAH)
 - HMC, a 76-bed, short-term acute facility
- HMC operates five provider-based entity (PBE) health centers
 - Four practices are off-campus and would be impacted by site neutrality
- In 2018, HMC engaged Stroudwater to compare the net impact on reimbursements under the following scenarios:
 - Scenario #1: Reimbursements received as PBEs under HMC both before and after implementation of 2019 OPPS Final Rule
 - Scenario #2: Reimbursements received as PB-RHC under HMC with more than 50 beds
 - Scenario #3: Reimbursements received as PB-RHC under HMC with fewer than 50 beds
 - Scenario #4: Stroudwater updated the analysis to factor the impact on reimbursements if the system converted the practices under the new RHC reimbursement methodology

Opportunity 1: Multi-hospital System (NY)

- The following table shows an average rate and reimbursements received from Medicare and Medicaid under each scenario:

Summary Data	Scenario #1 PBC	After 2019 OPPS Final Rule (PBC)	Before Change		
			Scenario #2 PB-RHC >50 Beds	Scenario #3 PB-RHC <50 Beds	Scenario #4 RHC Post 4/1/21
Medicare / Medicaid Average	\$ 143.17	\$ 127.65	\$ 82.30	\$ 183.42	\$ 126.81
Annual Visits	27,338	27,338	27,338	27,338	27,338
Reimbursements Received	\$ 3,913,934	\$ 3,489,588	\$ 2,249,917	\$ 5,014,296	\$ 3,466,732
340B Benefit	n/a	n/a	n/a	n/a	n/a
Variance w/ Before 2019 PBC (Scenario #1)		\$ (424,346)	\$ (1,664,017)	\$ 1,100,362	\$ (447,202)
Variance w/ After 2019 PBC (Scenario #1)			\$ (1,239,671)	\$ 1,524,708	\$ (22,856)

- Study Outcomes:**

- Before the change in the RHC reimbursement methodology, operating the five locations as PB-RHCs under a hospital with fewer than 50 beds led to the highest average reimbursement from Medicare and Medicaid
 - The change in the RHC reimbursement methodology would cause a negative net impact when compared to the reimbursements received under the current designation seen in Scenario #1
- If all five practices were off-campus, the net financial impact of the 2019 OPPS Final Rule would have gone from **(\$424K) to (\$1,313K)**

Opportunity 2: Mid-Atlantic Region

- HMB is a not-for-profit, 1,000-bed, multi-hospital system with regional health care centers providing services to more than 1 million people throughout the mid-Atlantic region
 - System includes, but not limited to:
 - A 600-bed short-term acute care facility
 - A 35-bed short-term acute care facility
 - A 25-bed critical access hospital (CAH)
 - A 25-bed critical access hospital (CAH)
 - A primary care physician group with more than 200 practice sites and 700 employed providers
- HMB engaged Stroudwater to quantify and compare the financial advantages and disadvantages of 3 practices currently designated as FSHCs with the PB-RHC designation under the following scenarios:
 - Scenario #1: Reimbursements received as a FSHC
 - Scenario #2: Reimbursements received as PB-RHCs aligned under the 35-bed PPS hospital
 - Scenario #3: Before Change - Reimbursements received as a PB-RHCs split between the two CAHs
 - Scenario #4: After Change - Reimbursements received as a PB-RHCs split between the two CAHs
- Due to location and proximity, none of the clinics could operate as a PBC under a CAH or receive an APC payment under a PPS hospital

Opportunity 2: Mid-Atlantic Region

- The following table shows an average rate and reimbursements received from Medicare and Medicaid under each scenario:

Summary Data	Scenario #1 FSHC	Before Change		After Change
		Scenario #2 PB-RHCs under STAC	Scenario #3 PB-RHCs under CAHs	Scenario #4 PB-RHCs under CAHs
Practices Impact				
Medicare / Medicaid Average	\$ 109.58	\$ 179.82	\$ 181.32	\$ 100.00
Annual Visits	75,174	75,174	75,174	75,174
Reimbursements Received	\$ 8,237,552	\$ 13,517,880	\$ 13,630,349	\$ 7,517,400
Critical Access Hospital Impact				
Medicare / Medicaid Reimbursement	\$ -	\$ -	\$ (1,879,112)	\$ (1,879,112)
340B Revenue	-	-	3,577,538	3,577,538
Reimbursements Received	\$ -	\$ -	\$ 1,698,426	\$ 1,698,426
Variance w/ FSHC (Scenario #1)		\$ 5,280,328	\$ 7,091,223	\$ 978,274

- Study Outcomes:**
 - Operating the three locations as PB-RHCs led to the highest average reimbursement from Medicare and Medicaid Before the change in the RHC reimbursement methodology
 - This option would also allow the clinics to pursue the 340B benefit
 - The STAC in Scenario #2 did not have a high enough DSH % to qualify for the 340B program

Opportunity 3: Independent Hospital

- ICMC is a 15-bed, not-for-profit Critical Access Hospital (CAH) that services approximately 10,000 residents
 - ICMC operates the following primary and specialty care clinics:
 - ICMC Family Care Clinic, which is designated as a Provider-Based Rural Health Clinic (PB-RHC)
 - ICMC Center Specialty Clinic on campus, which is designated as a Provider-Based Entity (PBE)
 - Specialty practice included 7 providers with a combined FTE of 0.8
- In 2018, ICMC engaged Stroudwater to compare the net impact on reimbursements under the following scenarios:
 - Scenario #1: Reimbursements received as a PB-RHC and PBE specialty practice under ICMC
 - Scenario #2: Before Change - Reimbursements received as an integrated PB-RHC (primary and specialty care) under ICMC
 - Scenario #3: After Change - Reimbursements received as an integrated PB-RHC (primary and specialty care) under ICMC

Opportunity 3: Independent Hospital

- The following table shows an average rate and reimbursements received from Medicare and Medicaid under each scenario:

Summary Data	Before Change		After Change
	Scenario #1 PB-RHC & PBE	Scenario #2 PB-RHC	Scenario #3 PB-RHC
Specialty Practice			
Medicare / Medicaid Average	\$ 217.55	\$ 235.57	\$ 174.30
Annual Visits	2,954	2,954	2,954
Reimbursements Received	\$ 642,655	\$ 695,874	\$ 514,882
Primary Care Practice			
Medicare / Medicaid Average	\$ 174.30	\$ 235.57	\$ 174.30
Annual Visits	7,378	7,378	7,378
Reimbursements Received	\$ 1,285,949	\$ 1,738,036	\$ 1,285,949
Combined Revenue:	\$ 1,928,604	\$ 2,433,910	\$ 1,800,831
Variance w/ PB-RHC & PBE (Scenario #1)		\$ 505,306	\$ (127,773)

- Study Outcomes:**
 - Before the change in the RHC reimbursement methodology, integrating the specialty practice (PBC) with the PB- RHC would have led to an increase in reimbursements of \$505K from Medicare and Medicaid
 - However, the change in the RHC reimbursement methodology means the hospital would have received \$128K less in reimbursements than currently received as a PBC

Opportunity 4: Multi-hospital System (MA)

- A two-hospital system that provides services to over 50,000 residents throughout multiple counties
 - Hospitals include:
 - A 134-bed, short-term acute facility
 - HMH, A 25-bed Critical Access Hospital (CAH)
- HMH entered into acquisition discussions with an independent 3-provider FSHC in the same town as the hospital
- HMH engaged Stroudwater to compare the net impact on reimbursements under the following scenarios:
 - Scenario #1: Reimbursements received as a free-standing independent physician practice
 - Scenario #2: Before Change - Reimbursements received as a PB-RHC under HMH with fewer than 50 beds
 - Scenario #3: After Change – Reimbursements received as a PB-RHC under HMH with fewer than 50 beds

Opportunity 4: Multi-hospital System (MA)

- The following table shows an average rate and reimbursements received from Medicare and Medicaid under each scenario:

Summary Data	Scenario #1 FSHC	Before Change	After Change
		Scenario #2 PB-RHC	Scenario #2 PB-RHC
Independent FSHC			
Medicare / Medicaid Average	\$ 97.03	\$ 197.89	\$ 100.00
Annual Visits	2,833	2,833	2,833
Reimbursements Received	\$ 274,889	\$ 560,622	\$ 283,300
Critical Access Hospital			
Medicare / Medicaid Reimbursement	\$ 10,044,434	\$ 9,971,421	\$ 9,971,421
340B Revenue	-	183,240	183,240
Reimbursements Received	\$ 10,044,434	\$ 10,154,661	\$ 10,154,661
Variance w/ FSHC (Scenario #1)		\$ 395,960	\$ 118,638

- Study Outcomes:**
 - Acquiring and operating the clinic as a PB-RHC under HMH would lead to an increase in reimbursements of \$396K from Medicare and Medicaid before the change in the RHC reimbursement methodology
 - Under the new RHC reimbursement methodology, the net benefit would have been reduced to \$119K and the gains would be solely dependent on 340B revenue

QUESTIONS

APPENDIX

- **Federally Qualified Health Center (FQHC)**

- An FQHC is an outpatient clinic where the main purpose is to enhance the provision of primary care services to patients from medically underserved urban and rural communities
 - In 1990, Section 4161 of the Omnibus Budget Reconciliation Act amended Section 1861(aa) of the Social Security Act (SSA) to add the FQHC benefit under Medicare
 - FQHCs include all organizations receiving grants under Section 330 of the Public Health Service Act (PHSA)
 - To qualify as an FQHC, the clinic must be owned by a public entity or a private non-profit
 - A municipally-owned healthcare entity can operate an FQHC within the system
- An FQHC receives the following reimbursement and additional funding opportunities
 - Enhanced reimbursement from Medicare, which is the lesser of 80% of charge or the FQHC PPS rate
 - Encounters with more than one FQHC practitioner on the same day constitute a single visit except under certain circumstances
 - FQHCs can apply geographic, new patient, and initial preventive physical examination (IPPE) or annual wellness visit (AWV) adjustments
 - Currently the Medicare PPS rate is adjusted by a factor of 1.3416 when the FQHC provides services to a new patient or to patient for Initial Preventative Physical Exam (IPPE) or an Annual Wellness Visit (AWV)
 - A new patient is one who has not received services at the FQHC, or by a provider associated with the FQHC, in the last three years

- **Federally Qualified Health Center (FQHC) (*continued*)**
 - Ability to participate in the 340B Drug Pricing Program
 - Access to 330 grant funding through the PHSA
 - Malpractice insurance premium savings due to Tort Reform
- An FQHC must agree to provide a very specific set of services provided by:
 - Directly by the applicant
 - Under a formal written agreement
 - The FQHC pays for service
 - Under a formal written referral arrangement/agreement
 - The FQHC does not pay for the service
- FQHCs that are Health Center Program Grantees or Look-Alikes must serve people from one of the Health Resources & Services Administration (HRSA)-designated areas:
 - Medically Underserved Area (MUA)
 - Medically Underserved Population (MUP)

- **Provider-Based Clinic (PBC)**

- A Provider-Based Clinic is operated as an integrated department of a main provider, including a hospital or CAH
 - PBC financial operations must be integrated with the main provider's financial system
 - The PBC must be held out to the public and other payers as a department of the main provider and patients must be made aware when they enter the PBE that they are entering a department of the main provider and will be billed accordingly
 - An off-campus CAH PBC must meet the federal distance requirement specified in the CAH Conditions of Participation or risk jeopardizing the CAH designation
 - The PBC must be 100% owned by the main provider
- PBCs and have access to the following benefits:
 - A physician clinic operating as an on-campus PBC can receive higher Medicare and Medicaid payments than the same practice operating as a freestanding clinic and often as an RHC
 - In 2019, off-campus PBCs will receive the same reimbursement as freestanding practices due to site neutrality
 - A PBC can participate in the 340B Drug Pricing Program
 - PBC physician practices operated as a department of a CAH receive a facility and a professional payment from Medicare, which can include a Method II election
 - For CAHs, Medicare reimburses the facility component based on an un-capped reasonable cost, as determined in the Medicare cost report
 - CAHs electing Method II will receive 115% of the Medicare physician services fee schedule for the professional portion of the claim

- **Rural Health Clinic (RHC)**

- A RHC is a clinic located in a rural, medically underserved area that has a separate reimbursement structure from a standard medical office
 - Reimbursement structure is an all-inclusive payment that includes provider and practice costs per visit, subject to a cap for free-standing RHCs and RHCs of hospitals larger than 49 beds
 - Starting April 1, 2021, all RHCs that were not grandfathered shall be subject to the same upper payment limit (UPL) regardless of whether the practice is owned and operated by a hospital with fewer than 50 beds
 - RHCs can be public, nonprofit, or for-profit healthcare facilities; however, they must be located in a non-urbanized area, as defined by the U.S. Census Bureau, and located in a federally designated shortage area (MUA, HPSA, or HPSP)
 - RHCs must employ a physician assistant (PA), certified nurse midwife (CNM), and/or nurse practitioner (NP) for at least 50% of the time that the practice is open to see patients
 - RHCs must be engaged in providing primary care services 50% or more of the time the clinic operates

- **Rural Health Clinic (RHC) (*continued*)**
 - A PB-RHC is an RHC meeting the criteria of a PBE
 - 42 CFR 405.2401(b) excludes RHCs from the list of PBEs that must meet CAH distance requirement
 - A PB-RHC must be 100% owned by main provider and financial operations must be integrated with the main provider's financial system
 - The PB-RHC must be held out to the public and other payers as a department of the main provider and patients must be made aware when they enter the PBE that they are entering a department of the main provider and will be billed accordingly
 - Prior to April 1, 2021, RHCs that operate as provider-based departments of hospitals with fewer than 50 beds, including CAHs, could receive higher Medicare and Medicaid reimbursements than practices operating as a freestanding clinic or RHC
 - Those hospitals received an un-capped AIR for services provided due to cost-based reimbursement methodology for Medicare and Medicaid
 - Those hospitals can also participate in the 340B Drug Pricing Program so long as the hospital that owns and operates RHCs qualify

- **Free-Standing Health Clinic (FSHC)**

- An FSHC is a physician practice that is not operated as a department of a main provider, including a hospital or CAH
 - An FSHC can be located anywhere and does not bring to question distance requirements for CAH eligibility
 - An FSHC does not require staffing by mid-levels
- FSHCs must bill under the Medicare Physician Fee Schedule and are not eligible for the 340B program
- An FSHC is a non-cost-based department of a Critical Access Hospital
 - An FSHC operating under a CAH will carve out administrative cost from cost-based departments and re-allocate the expense to a non-cost-based department
 - An off-site FSHC will not jeopardize or bring to question the federal distance requirements of a CAH

- **Critical Access Hospital (CAH)**
 - The clinic designation type selected will not only impact reimbursements received, but could also jeopardize the ability to maintain CAH designation
 - Each CAH must comply with the following, in addition to other, conditions of participation (COPs):
 - Meet federal distance requirement that a CAH must be at least a 35-mile drive on primary roads or 15 miles on secondary roads to the nearest hospital or CAH
 - A CAH acquiring an off-site PBE, unless the entity is a PB-RHC, is required to meet distance requirements based on the location of the acquired entity
 - Section 42 CFR 413.65(e)(3)(i) requires all off-campus provider-based facilities to be located within a 35-mile radius of the campus of the hospital or CAH that is the potential main provider
 - **Already-established RHCs are excluded from** the list of off-campus facilities subject to **this provision**
 - Further, section 42 CFR 485.610(e)(2) requires that if a CAH operates an off-campus provider-based facility as defined in §413.65(a)(2), except for a rural health clinic (RHC), that was created or acquired on or after January 1, 2008, then the off-campus location must meet the federal distance requirement to the next nearest hospital or CAH
 - 42 CFR 405.2401(b) excludes already-established RHCs from the list of provider-based facilities that must comply with this requirement
 - 42 CFR 413.65(a)(2) defines a campus as the physical area immediately adjacent to the provider's main buildings, other areas, and structures that are not strictly contiguous to the main buildings, but are located within 250 yards of the main buildings, and any other areas determined by the CMS regional office on an individual case basis to be part of the provider's campus
 - Operating a provider-based facility which does not meet the distance requirements would lead to the loss of their CAH designation even if the CAH is designated as a necessary provider



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