



If you have a question at any time, click the button by your name on the list of participants to raise your hand.

Andrea will call on you.

Magnetic Resonance Imaging (MRI) Methodology Workgroup

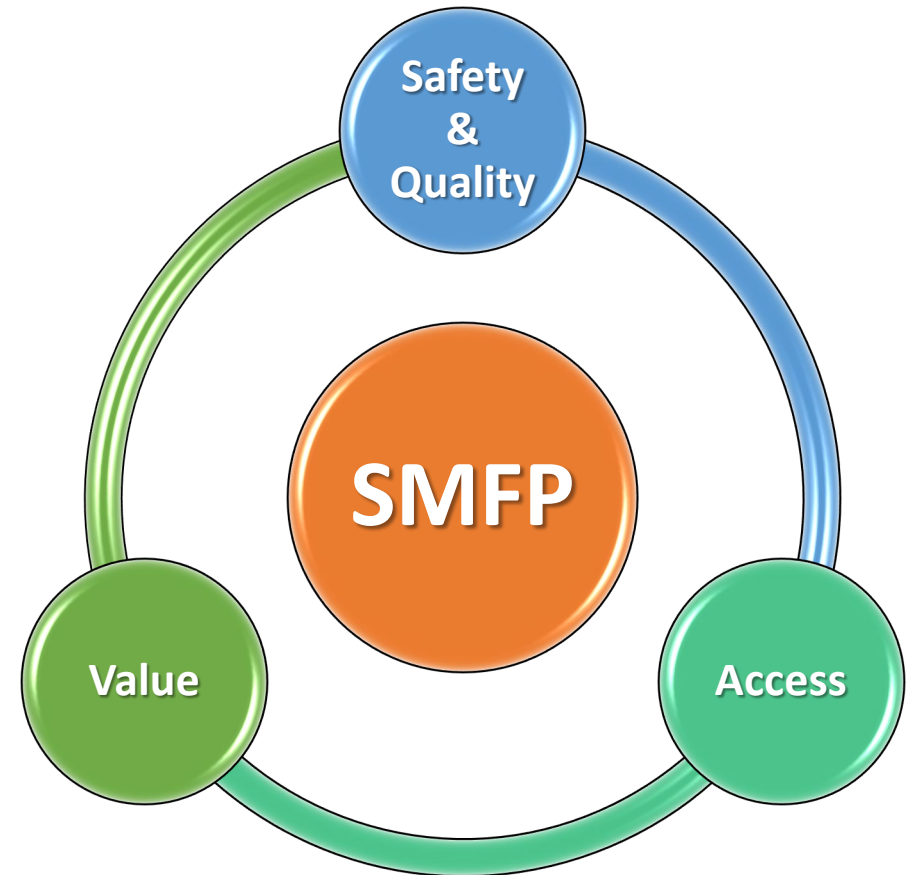
November 15, 2021

Methodology Basics

- Mathematical calculations based on certain assumptions
 - At what point in the utilization (capacity) of a scanner should the addition of scanners be considered
- Goals
 - Assure that services are reasonably available throughout the state (access)
 - Avoid unnecessary duplication of services (value)
- Applied to all service areas in the state
 - Designed to work well in almost every service area
 - Where the methodology does not work well, a person can file a petition in July for an exception to the methodology

Basic Principles

- SMFP, Chapter 1
- Govern all methodologies
- Aspirational
 - Maximize the likelihood of adhering to these principles
- Methodologies should not reflect aspects of specific counties or providers



Methodology Revision Process



Three documents/processes govern development of MRI scanners

- State Medical Facilities Plan
- Certificate of Need (CON) law
 - Not on the table
- CON Regulations (Rules) – NC Administrative Code (NCAC)
 - Can recommend changes, but these are not under purview of SHCC
 - CON proposes changes to Rules Review Commission

CON Law: § 131E-176

- CON application must be pursuant to need determination in the SMFP
- Defines the equipment that requires a certificate of need
 - No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department...”
 - The acquisition by purchase, donation, lease, transfer, or comparable arrangement of any of the following equipment by or on behalf of any person:
 - 7. Magnetic resonance imaging scanner.
 - (14m) Magnetic resonance imaging scanner. – Medical imaging equipment that uses nuclear magnetic resonance.
 - (16s) The furnishing of mobile medical equipment to any person to provide health services in North Carolina, which was not in use in North Carolina prior to the adoption of this provision, if the equipment would otherwise be subject to review in accordance with sub-subdivision f1. of this subdivision or sub-subdivision p. of this subdivision if it had been acquired in North Carolina.
- SL 2021-19 (SB462), effective 10/1/2021, changed CON dollar thresholds for new institutional health service, diagnostic center, major medical equipment, etc. – not relevant to MRI because they always require a CON.
- SL 2021-19 amended GS 131E-189
 - Generally, CONs will expire after 2 years if the holder does not execute or commit to a contract for design services for the project. Projects approved before 10/1/2021 have until 10/1/2023 to comply.
 - Includes provisions to extend time for situations that arise that are not under the control of the certificate holder.

CON Regulations: 10A NCAC 14C .2701, .2703

- Provides information for people applying for MRI scanners
- Distinguishes between mobile and fixed scanners
- Sets out requirements for CON applications. Applicants must:
 - demonstrate the need in the service area
 - show that they can meet the need based on the performance standards in the Rules

Proposed Changes to Rules

- Proposed changes are published in the Rules Review Commission Register
 - [NC OAH: NC Register Volume 36 Issue 02](#)
 - Rules Review Commission will meet on December 16, 2021
- 10A NCAC 14C .2701
 - MRI capacity definitions have been removed
 - New definition
 - “ ‘Adjusted MRI procedure’ shall have the same meaning as defined in the” SMFP
- 10A NCAC 14C .2703
 - Primary proposed change is to performance standards for fixed scanners
 - 70% of current need determination threshold, rather than 100% of threshold.
- Workgroup can have input into changes to these definitions and standards
 - Topic for later



Current MRI Methodology: Basics

Coverage of Methodology

- Methodology calculates need for new fixed scanners only.
- No methodology for Mobile scanners.
 - Must submit summer petition for new mobile scanner.
- Methodology is not relevant for replacement scanners.
 - Need determination not required to replace a scanner

Types/Locations of MRI Services

- Hospitals
 - Includes imaging centers in facilities that are on the hospital license (on a hospital campus)
- “Freestanding” Imaging Centers
 - Not in a hospital
 - Imaging center may be owned by a hospital/health system, but not on the hospital’s license or campus
- Medical/surgical Practices
 - Orthopedic, neurology are most common
- Mobile
 - Serve all above locations
- “Parked/installed” mobiles
 - Legacy mobiles (pre-CON law) that received a Declaratory Ruling from Division of Health Service Regulation to convert a mobile to a *de facto* fixed.
 - Complete “Fixed” R&I form and are considered fixed in methodology calculations.

Current Policies

- Policies govern equipment throughout the state.
- TE-2: Intraoperative MRI (iMRI)
 - Conditions under which a facility may apply to obtain an iMRI
 - Not in planning inventory or methodology
- TE-3: Plan Exemptions for Fixed MRIs
 - Hospital with 24/7 emergency care can apply if it does not have existing or approved fixed MRI, without regard to need determination
 - CON application must demonstrate that scanner can perform at least 850 weighted scans by third year of operation; CON performance standards would not apply (10A NCAC 14C.2703)
 - Must be located on hospitals main campus but does not have to be in the hospital building (e.g., can be in imaging center located on main campus)
 - In planning inventory and methodology
- AC-3: Academic Medical Center Teaching Hospitals
 - Sets out conditions under which these facilities can obtain equipment for teaching and research purposes
 - Will need to discuss these soon when we have a more detailed discussion of policies.

Specialized Scanners (Table 17E-2)

- No need determination, not in planning inventory
 - Have CON to operate scanner for specific purpose (pediatric) or in specific location only (e.g., children's hospital, oncology suite)
 - Some are AC-3 scanners – in teaching hospitals
 - Except for iMRI, SMFP policies do not address these scanners
 - Tacit assumption: these scanners will stay “specialized” in perpetuity
- Table may also include scanners that are part of a demonstration project.
 - Scanners will go into inventory and methodology once demonstration is concluded
 - Do not currently have any demonstration projects

Methodology Calculations

Methodology Steps

- Define Service Areas
- Prepare Planning Inventory
- Identify Planning thresholds
- Weight the Procedures
- Perform Calculations

Figure 5.1
Acute Care Bed
Service Areas



Shaded counties are multicity acute care bed service areas, which consist of a county with one or more hospitals and a nearby county without an acute care hospital.

The asterisk (*) in multicity service areas denotes the county with at least one hospital.

Hospitals	Multicity Service Area	Color Code
CarolinaEast Medical Center	Craven, Jones, Pamlico	
Duke Regional Hospital, Duke University Hospital, North Carolina Specialty Hospital	Durham, Caswell	
Erlanger Murphy Medical Center	Cherokee, Clay	
Halifax Regional Medical Center	Halifax, Northampton	
Maria Parham Health	Vance, Warren	
Mission Hospital	Buncombe, Graham, Madison, Yancey	
Sentara Albemarle Medical Center	Pasquotank, Camden, Currituck, Perquimans	
Vidant Medical Center	Pitt, Greene, Hyde, Tyrrell	
Vidant Roanoke-Chowan Hospital	Hertford, Gates	

Initial Step: Prepare Inventory of Fixed & Mobile Scanners

- Hardest part of methodology
 - Equipment is not licensed, so there is no official list of every fixed scanner in the state or every mobile scanner authorized to be in the state
 - The CON Project ID number helps
 - Some are “Legacy” (i.e., grandfathered) scanners because they pre-date the CON law
 - Most are mobile
- Data Sources
 - Hospital License Renewal Application – for scanners owned and operated by hospitals
 - Registration and Inventory Forms – others
 - Report by Federal fiscal year 10/1 through 9/30
- How do we (hope that we) find all the scanners?
 - Hospitals – on the LRA (almost always)
 - Freestanding Imaging Centers and Mobile
 - List of email addresses for the person who submitted the R&I form last year
 - Mobile scanners may or may not always be in NC every year
 - Verify against previous year and any new CONs - manually
 - In general, providers who report on the R&I forms are good about letting us know about temporary and permanent replacements for scanners
- Planning created internal ID for each mobile scanner and each fixed scanner in a freestanding imaging center. This has helped.

Planning Thresholds - Assumptions

- Full capacity of a scanner is 6,864 “basic” scans (30 minutes or 2 scans per hour, staffed 66 hours per week for 52 weeks per year: $66 \times 52 \times 2 = 6,864$)
- Based on % utilization required to trigger a need for an additional scanner: 100% = 6,864
- Service areas with more equipment should be able to achieve higher level of efficiency
 - These areas also tend to have larger population

Number of Fixed Scanners in Service Area	Planning Threshold	Inpatient and Contrast Adjusted Thresholds
4 and over	70.0%	4,805
3	65.0%	4,462
2	60.0%	4,118
1	55.0%	3,775
0	25.0%	1,716

Weighting

- Scans are weighted based on use of contrast/sedation and whether inpatient or outpatient
 - Outpatient “basic” scan without contrast : not weighted (weight=1.0)
 - Inpatient “basic” scans: weighted 0.4 times longer than outpatient
 - Contrast or sedation: weighted 0.4 times longer than “basic”

Procedure Type	Base Weight	Inpatient Weight	Contrast Weight	Procedure Time in Minutes	Calculation
Outpatient - No Contrast/Sedation	1.0	0.0	0.0	30	30 x 1.0
Outpatient - with Contrast/Sedation	1.0	0.0	0.4	42	30 x 1.4
Inpatient - No Contrast/Sedation	1.0	0.4	0.0	42	30 x 1.4
Inpatient - with Contrast/Sedation	1.0	0.4	0.4	54	30 x 1.8

Methodology

- Create the planning inventory
 - List all fixed scanners at each location.
 - Organized by service area (acute care hospital service areas)
 - Each fixed scanner counts as “1 fixed equivalent” scanner.
- Assign a fixed equivalent value of 1 to all CON-approved scanners not yet developed
 - Placeholders for need determinations appear in Table 17E-1 as a fixed scanner with no procedures
 - The placeholder will not show a provider if the CON has not yet been issued
- List all sites served by mobile scanners and assign “fixed equivalents”
 - Divide the number of scans performed at each site by the threshold for the service area
 - E.g., A service area has 2 scanners and a mobile site that performs 1,537 scans.
 - Fixed equivalent = $1,537/4,118 = .37$
 - Values are rounded for display, but internal calculations do not use rounding

Table 17E-1: List Facilities/Sites

A	B	C	D
Service Area	Service Type	CON #	Service Site (Provider/Owner)
County	Hospital fixed	A-111111-03	BIG Hospital - Main Campus
County	Hospital fixed		BIG Hospital - Satellite Campus Imaging Center
County	Freestanding fixed	E-000001-18	Imaging Center (Imaging Center, LLC)
County	Mobile	E-000001-04	Radiology Provider (Radiology Provider, LLC)
County	Mobile	Legacy	Orthopedic Practice (OrthoPod, PA)

Shows all types of scanners. Not all counties have all types.

Do not always have CON #.

Provider/owner identified for freestanding fixed and mobile only

Wording reflects data source – the name is whatever is on the LRA/R&I form.

Assign Fixed Equivalent Weights

A	B	D	E	F	G
Service Area	Service Type	Service Site (Provider/Owner)	Fixed Magnet	Fixed Equiv.	Total MRI Scans
County	Hospital fixed	Main Hospital Campus	1	1.00	3,191
County	Hospital fixed	Hospital Satellite Campus	1	1.00	1,050
County	Freestanding fixed	Imaging Center (Imaging Center, LLC)	1	1.00	250
County	Mobile	Radiology Provider (Radiology Provider, LLC)	0	0.42	1,895
County	Mobile	Orthopedic Practice (OrthoPod, PA)	0	0.34	1,537
TOTAL			3	3.76	7,923

3 scanners = 4,462 threshold

$$1,537 / 4,462 = 0.34$$

Perform Calculations & Determine Need

$$\begin{aligned}
 &1,369 + (794 \times 1.4) + (782 \times 1.4) + (246 \times 1.8) \\
 &= 1,369 + 1,111.6 + 1,094.8 + 442.8 \\
 &= 4,018.2
 \end{aligned}$$

B	E	F	G	H	I	J	K	L	M	N	O
Service Type	Fixed Magnet	Fixed Equiv.	Total MRI Scans	OP No C/S	OP C/S {1.4}	IP No C/S {1.4}	IP C/S {1.8}	Adj Total	Area Avg. Procs.	Thresh -old	MRI Need
Hospital fixed	1	1.00	3,191	1,369	794	782	246	4,018			
Hospital fixed	1	1.00	1,050	689	361	0	0	1,194			
FS Fixed	1	1.00	250	250	0	0	0	250			
Mobile	0	0.42	1,895	1,416	479	0	0	2,087			
Mobile	0	0.34	1,537	1,457	80	0	0	1,569			
TOTAL	3	3.76	7,923					9,118	2,425	4,462	0

$$9,118 / 3.76 = 2,425$$



Data

Data

Available

- Utilization
 - Number of scans
 - inpatient/outpatient
 - with/without contrast
 - Fixed and mobile
- Type of facility/equipment
 - Fixed/mobile
 - Hospital/freestanding center
- Total hours of operation per year for freestanding fixed and mobile
- Population by county and age

Not Available

- CPT Codes
- MRI utilization by age group
- Payer mix
- Complete patient origin
 - Mainly have fixed (hospital and freestanding)
 - Have data for mobile scanners owned and operated by the hospital
- Measures of MRI need in the general population

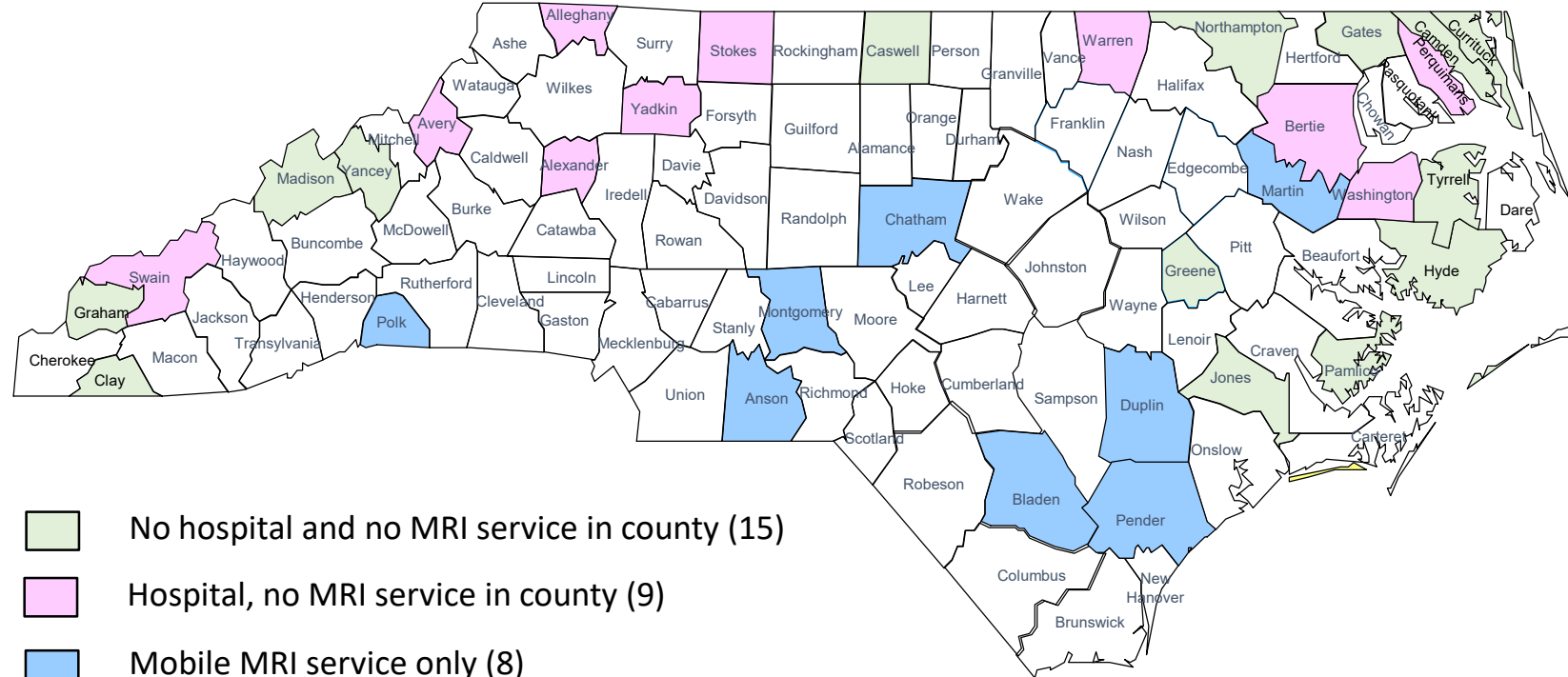
MRI Units in North Carolina (2022 SMFP)

• Hospital fixed	182	Scanners per capita (100,000)	
• Freestanding fixed	69	• Fixed scanners	23.5
• Hospital owned & operated mobiles	10	• Mobile scanners	5.8
• All other mobiles*	52	• Total	29.4
• Placeholders (prior year need or CON approved)	15	• Including approved	30.8
		US (2019) **	40.4

* Mobile scanners that served the state in 2020. Each mobile scanner is counted once, regardless of the number of service sites. Consider the number of mobile scanners as an estimate.

** Organisation for Economic Co-operation and Development -OECD (2021), Magnetic resonance imaging (MRI) units (indicator). doi: 10.1787/1a72e7d1-en (Accessed on 11 November 2021)

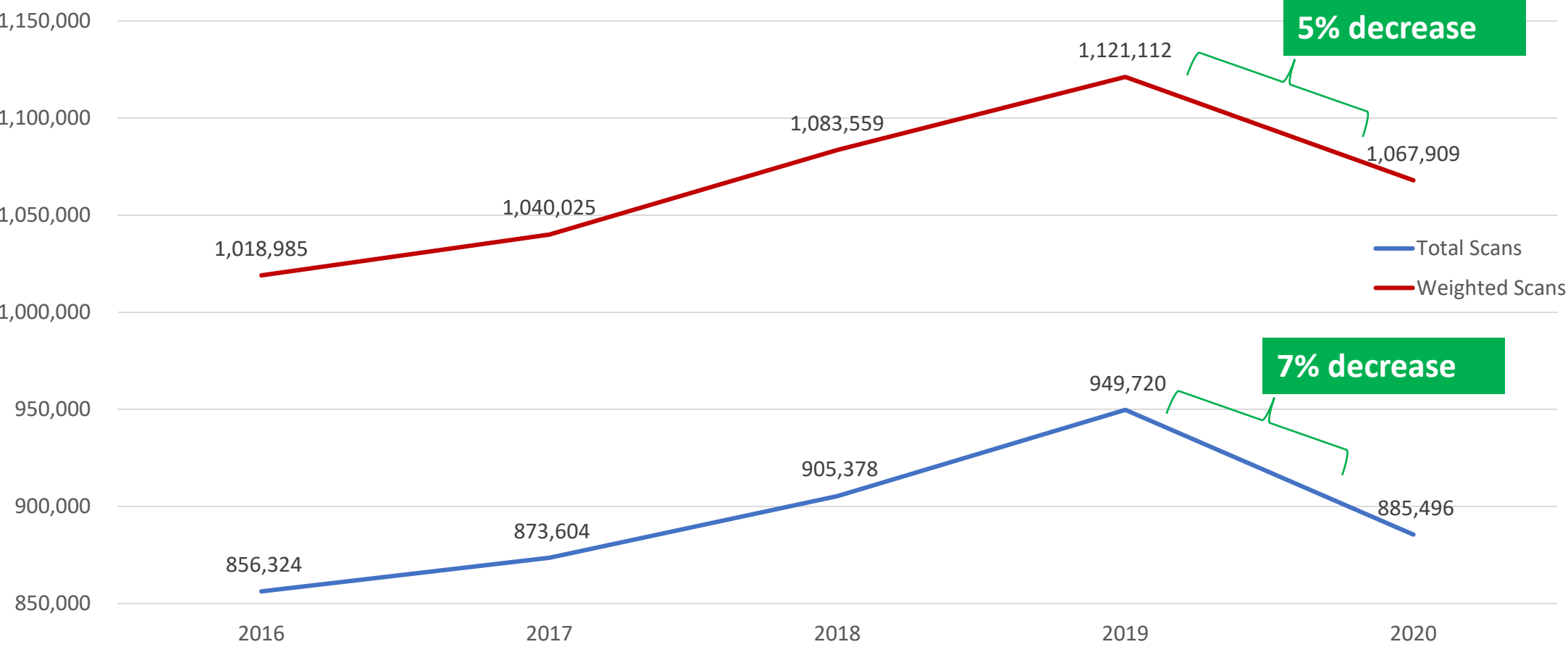
MRI Service by County, 2022 SMFP



- No hospital and no MRI service in county (15)
- Hospital, no MRI service in county (9)
- Mobile MRI service only (8)
- Has fixed MRI service

- The hospitals in Alexander and Yadkin counties are closed.

Total and Weighted MRI Scans, 2016-2020



Staff Ideas about a Revised Methodology

Sample of General Structure of Revised Methodology

1

Prepare inventory
(incorporate
assumptions)

2

Apply weights to
procedures

3

Calculate growth

4

Calculate projected
utilization for
projection year

5

Apply thresholds to
calculate deficits and
surpluses for service
area

6

Determine need for
service area

Initial Staff Thoughts on Revisions

- Does the state need more scanners or does the SMFP need a more rational methodology to project need? Or both?
- Need to change “philosophy” of MRI methodology
 - Methodologies should project future need
 - Current methodology calculates need as of 2 years before current SMFP
 - What year should be the “projection year?”
- Possible basis for projection (based on available data)
 - May use a multi-year “look-back” of utilization as basis for projection
 - County population growth (may look at single or multiple years)
 - Limit to adult population only?
- May need to adjust
 - Capacity/Thresholds
 - Weights
- How to include mobile scanners
 - Does conceptualization of mobile utilization as “fixed equivalents” make sense?