MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS) MEGAVOLTAGE RADIATION THERAPY SERVICES/UNITS STANDARD ADVISORY COMMITTEE (MRTSAC) MEETING

Thursday, August 30, 2018

South Grand Building 333 S. Grand Ave, 1st Floor, Grand Conference Room Lansing, MI 48933

APPROVED MINUTES

I. Call to Order

Chairperson Kastner called the meeting to order at 9:30 A.M.

A. Members Present:

Brian Kastner, MD, Chairperson – Spectrum Health
Ahmed Akl, MD – Genesee County Radiation Oncology
June Chan, MD – Michigan Radiological Society (arrived at 9:40 a.m.)
Paul J Chuba MD, Ph.D. – St John Providence Health Systems
Lucan DiCarlo, DO – Sparrow Hospital
Roberta Elliott – Spectrum Health's Cancer Health & Executive Patient
and Family Advisory Councils (PFAC)
Courtney Friedle – MidMichigan Health
Adeeb Harb – Detroit Medical Center (arrived at 9:33 a.m.)
James A. Hayman, MD – University of Michigan Health System (arrived at 9:33 a.m.)
Gwendolyn H. Parker, MD – Blue Cross Blue Shield of Michigan
Walter M. Sahijdak, – MD Trinity Health-Michigan
Salim M Siddiqui, MD, Ph.D. – Henry Ford Health System
Anita A. Stolaruk – ProMedica Monroe Regional Hospital

B. Members Absent:

Michele L. Davis – Electrical Workers' Insurance Fund

C. Michigan Department of Health and Human Services Staff present:

Tulika Bhattacharya (arrived at 9:35 a.m.) Amber Myers Beth Nagel Tania Rodriguez Brenda Rogers

II. Declaration of Conflicts of Interests

None.

III. Review of Agenda

Motion by Dr. Siddiqui, seconded by Dr. Parker to accept the agenda as presented. Motion Carried.

IV. Review of Draft Minutes – July 26, 2018

Motion by Dr. DiCarlo, seconded by Dr. Akl to accept the minutes as presented. Motion Carried.

V. Review of Impact of Proposed Weights

Dr. Siddiqui provided an overview (Attachment A).

Dr. Sahijdak provided an overview of ETV calculations and the 15-minute base (Attachment B).

Discussion followed.

Beth reminded that it's only 30% non-compliant when rural/micro are calculated in.

Motion by Dr. Siddiqui, seconded by Dr. Chuba to maintain the 15-minute base for the ETV weighting and to adopt the following revised weights:

•	Treatment Visit Category	•	2016 Weight	•	Time for Typical Treatment	•	Revised Weight Option 2
•	Simple*	•	1	•	10 min	•	0.66
•	Intermediate*	•	1.1	•	15 min	•	1
•	Complex**	•	1.25	•	30 min	•	2
•	IMRT**	•	2	•	25 min	•	1.66
•	Total Body Irradiation	•	8	•	75 min	•	5
•	HMRT Therapy	•	5	•	50 min	•	3.33
•	SRS/SBRT	•	8	•	60 min base	•	4
•	IORT	•	20	•		•	20
•	Gating	•	+1	•	+15 min	•	+1
•	SRS/SBRT Additional Isocenters	•	NEW	•	+20 min per isocenter	•	+1.33 per additional isocenter

_	uided Real Time ng w/o Adaptive	•	NEW	•	+30 min	•	+2
	uided Real Time ng Radiation WITH ve	•	NEW	•	+45 min	•	+3
Patien	t Specific QA for iMRT	•	NEW	•	30 min	•	2.0 (limited to once per plan, not to exceed twice per course)
Patien SRS/S	t Specific QA for BBRT	•	NEW	•	45 min	•	3.0 (limited to once per plan, not to exceed twice per course)

Discussion followed.

Public Comment

1. Patrick O'Donovan, Beaumont Health (Attachment C)

Discussion on motion continued.

Motion carried in a vote of 13 - Yes, 0 - No, and 0 - Abstained.

Recessed at 10:43 a.m. and reconvened at 10:55 a.m.

VI. Review of Volume Requirements

Dr. Kastner provided an overview (Attachment A).

Discussion followed.

Motion by Dr. Chuba, seconded by Dr. Akl motion to change maintenance volume requirements to 4,000 ETVs per unit annually for metropolitan, micropolitan and rural counties.

Motion by Dr. Hayman, seconded by Ms. Friedle to amend Dr. Chuba's original motion to include studying the impact of changing maintenance to 4,000 for metropolitan, micropolitan and rural counties before adopting the motion. Motion failed in a vote of 6 - Yes, 7 - No, and 0 - Abstained.

A vote on the original motion carried in a vote of 9 - Yes, 4 - No, and 0 Abstained.

VII. Next Steps

Definitions are needed for the new treatment visit categories: MR-Guided Real Time Tracking w/o Adaptive, MR-Guided Real Time Tracking Radiation with Adaptive, Patient Specific QA for iMRT, and Patient Specific QA for SRS/SBRT.

Review volume requirements for initiation, expansion, and relocation.

VIII. Future Meeting Dates – October 3, 2018; November 1, 2018; November 29, 2018, & December 19, 2018

Chairperson Kastner reviewed the meeting schedule.

IX. Public Comment

None.

X. Adjournment

Motion by Dr. Sahijdak, seconded by Dr. Siddiqui to adjourn the meeting at 11:50 a.m.

Equivalent treatment visit calculations

Walter M Sahijdak MD MBA Trinity Health

Section 11. Equivalent treatment visits

Sec. 11. Equivalent treatment visits shall be calculated as follows:

- (1) For the time period specified in the applicable sections, assign each actual treatment visit provided to one applicable treatment visit category set forth in Table 1.
- (2) The number of treatment visits for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding equivalent treatment visits weight in Table 1 to determine the number of equivalent treatment visits for that category for that time period.
- (3) The number of equivalent treatment visits for each category determined pursuant to subsection (2) shall be summed to determine the total equivalent treatment visits for the time period specified in the applicable sections of these standards.

ETV annual calculation (Non-special units)

- Multiply each treatment visit category weight by number of treatment visits in the category over a year.
- Sum the ETV's in each category for the total ETV amount

TABLE 1 Equivalent Treatments

Treatment Visit Category	Non-Special Visit Weight	Special Visit Weight
Simple	1.00	
Intermediate	1.10	
Complex	1.25	
IMRT	2.00	
Total Body Irradiation	8.00	8.00
HMRT Therapy		5.00
Stereotactic radio-surgery/radio-therapy*	8.00	8.00
(non-gamma knife and cyber knife**)		
Gamma Knife**		8.00
IORT		20.00

All patients under 5 years of age receive a 2.00 additive factor.

^{*}After the first visit, each additional visit receives 2.5 additional equivalent treatment visits with a maximum of five visits per course of therapy.

^{**}After the first isocenter, each additional isocenter receives 4 additional equivalent treatment visits.

Treatment visit category weight conversion to room time

- 1.0 = 15 minutes of room time
- 2.0 = 30 minutes of room time

Total possible ETV's per day

- During an eight hour day, there are 32 sessions of room time with each lasting fifteen minutes, the length of a simple treatment visit
- ETV per hour (4) x 8 hours = 32 ETV/day

Total possible ETV's per week

- Standard Radiation Treatment is administered
 5 days/week (Treatment is not commonly administered on Saturdays and Sundays)
- ETV per day (32) x 5 days = 160 ETV/week

Total possible ETV's per year

- Treatment weeks/year is only 50 (Assumption is that ~2 weeks or 10 weekdays are not in use to account for holidays, etc.)
- 160 ETV per week x 50 weeks = **8000** ETV/year

Compliance minimum for annual ETV

- (4) Compliance with the following monitoring and reporting requirements:
- (a) Non-special MRT units and HMRT units shall be operating at a minimum average volume of 8,000 Equivalent Treatment Visits per unit annually by the end of the third full year of operation, and annually thereafter. All special purpose MRT units shall be operating at a minimum average volume of 1,000 equivalent treatment visits per special purpose unit by the end of the third full year of operation, and annually thereafter. An applicant shall not include any treatments conducted on a dedicated research MRT unit.
- (b) Non-special MRT units and HMRT units approved pursuant to Section 4(2) of these standards shall be operating at a minimum average volume of 5,500 equivalent treatment visits per unit by the end of the third full year of operation, and annually thereafter. An applicant shall not include any treatments conducted on a dedicated research MRT unit.

Compliance minimum for annual ETV

- (4) Compliance with the following monitoring and reporting requirements:
- (a) Non-special MRT units and HMRT units shall be operating at a minimum average volume of 8,000 Equivalent Treatment Visits per unit annually by the end of the third full year of operation, and annually thereafter. All special purpose MRT units shall be operating at a minimum average volume of 1,000 equivalent treatment visits per special purpose unit by the end of the third full year of operation, and annually thereafter. An applicant shall not include any treatments conducted on a dedicated research MRT unit.
- (b) Non-special MRT units and HMRT units approved pursuant to Section 4(2) of these standards shall be operating at a minimum average volume of 5,500 equivalent treatment visits per unit by the end of the third full year of operation, and annually thereafter. An applicant shall not include any treatments conducted on a dedicated research MRT unit.

ETV to replace an MRT

- Sec. 5. Replacement of an existing MRT unit means an equipment change that results in a new serial number or requiring the issuance of a new radiation safety certificate from the State of Michigan Radiation Safety Section. Replacement also means the relocation of an MRT service or unit to a new site. Replacement does not include an upgrade to an existing MRT unit with the addition or modification of equipment or software; the replacement components; or change for the purpose of maintaining or improving its efficiency, effectiveness, and/or functionality. An applicant requesting to replace an existing MRT unit(s) or MRT service shall demonstrate the following, as applicable to the proposed project.
 - (1) An applicant proposing to replace an existing MRT unit(s) shall demonstrate the following:
 - (a) The replacement unit(s) is the same type as the MRT unit(s) to be replaced.
- (b) The MRT unit(s) to be replaced is fully depreciated according to generally accepted accounting principles or either of the following:
 - (i) The existing MRT unit(s) poses a threat to the safety of the patients.
- (ii) The replacement MRT unit(s) offers technological improvements that enhance quality of care, increased efficiency, and a reduction in operating costs and patient charges.
- (c) The applicant agrees that the unit(s) to be replaced will be removed from service on or before beginning operation of the replacement unit(s).
- (2) An applicant proposing to replace an existing MRT service to a new site shall demonstrate the following:
 - (a) The proposed site is within the same planning area as the existing MRT service site.
- (b) The existing MRT unit(s) shall be operating at the following volumes, as applicable to the proposed project:
- (i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit approved under Section 4(2).

ETV to add an MRT

Section 6. Requirements to expand an existing MRT service

- Sec. 6. An applicant proposing to expand an existing MRT service by adding an MRT unit(s) shall demonstrate the following, as applicable to the proposed project.
- (1) An applicant proposing to add a non-special MRT unit(s) shall demonstrate an average of 10,000 equivalent treatment visits was performed in the most recent 12-month period on each of the applicant's existing and approved non-special MRT units.
- (2) An applicant proposing to expand an existing MRT service with a special purpose MRT unit shall demonstrate the following, as applicable to the proposed project:
- (a) An average of 8,000 equivalent treatment visits was performed in the most recent 12-month period on each of the applicant's existing and approved non-special MRT units.
- (b) An applicant proposing to add a dedicated total body irradiator shall operate a bone marrow transplantation program or have a written agreement to provide total body irradiation services to a hospital that operates a bone marrow transplantation program.
- (c) An applicant proposing to add a dedicated stereotactic radiosurgery unit such as a gamma knife or cyber knife, shall demonstrate that the applicant has a contractual relationship with a board-eligible or board-certified neurosurgeon(s) trained in stereotactic radiosurgery and on-site 3-dimensional imaging and 3-dimensional treatment planning capabilities.
- (d) An applicant proposing to add an intraoperative MRT unit in an existing or proposed hospital operating room shall demonstrate that the unit is a linear accelerator with only electron beam capabilities.

ETV interpretation

- 8000 ETV machine in use 8hours/day
- 5500 ETV (rural/micropolitan) in use 5.5 hr/d
- 10000 ETV (replacement) in use 10 hr/d

2018 MRTSAC Review of ETV's Using Revised Weighting

M Salim U Siddiqui, MD, PhD

Senior Staff Physician

Director, Stereotactic Radiation Program

Director, MR Simulation Program

Department of Radiation Oncology

Medical Director, HFCI Physician Partnering

Medical Director, HFCI Northwest Region

Henry Ford Cancer Institute
Henry Ford Health System

Treatment Times (in minutes)

Treatment Visit Category	Α	В	С	D	E	F	G	н	1
Simple*	15	15	10	10	15	10	10	10	10
Intermediate*	15	15	15	15	15	15	15	15	15
Complex**	40	15-30	20	15	20	30	30	30	20
IMRT**	40	15-30	20-25	15	30	20	20	20	25
IGRT + Treatment	-	-	-	-	20	-	-	-	-
OSMS + Treatment	-	-	-	-	30	-	-	-	-
Total Body Irradiation	60-90	60-90	60-90	NA	-	-	-	-	-
HMRT Therapy	-	-	-	NA	-	-	-	-	-
SRS/SBRT	30-90	30-90	30	30	SRS 60 SBRT 45	60	60	60	45
SRS Special Unit	-	-	-	-	-	-	-	90	-
Peds slot	-	-	40	NA	-	-	-	-	-
Additional time for breath hold treatment	-	-	5 to 10	5	30	-	-	-	-
IORT	-	-	-	-	-	-	-	-	-

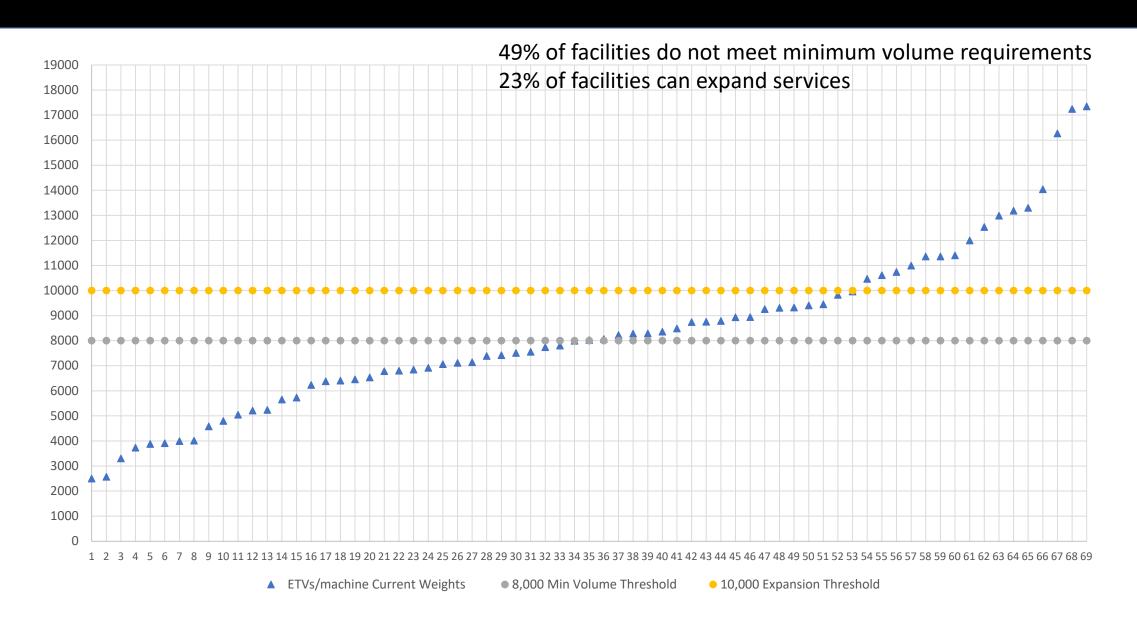
Additive Factors

	Α	В	С	D	E	F	G	н	
Gating	+15 min	+15 to 30 min							
MR-Guided Real Time Tracking w/o Adaptive	+30 min								
MR-Guided Real Time Tracking Radiation WITH Adaptive	+45 min								40 min
Patient specific QA for IMRT	20 to 30 min		20 to 30 minutes	60 minutes	60 min	15 min	15 min	15 min	70 min
Patient specific QA for SRS	60 min		60 minutes	Patient specific QA for SRS	45 min	15 min	15 min	15 min	90 min
Patient specific QA for SBRT	60 min		60 minutes	10 minutes	45 min	15 min	15 min	15 min	

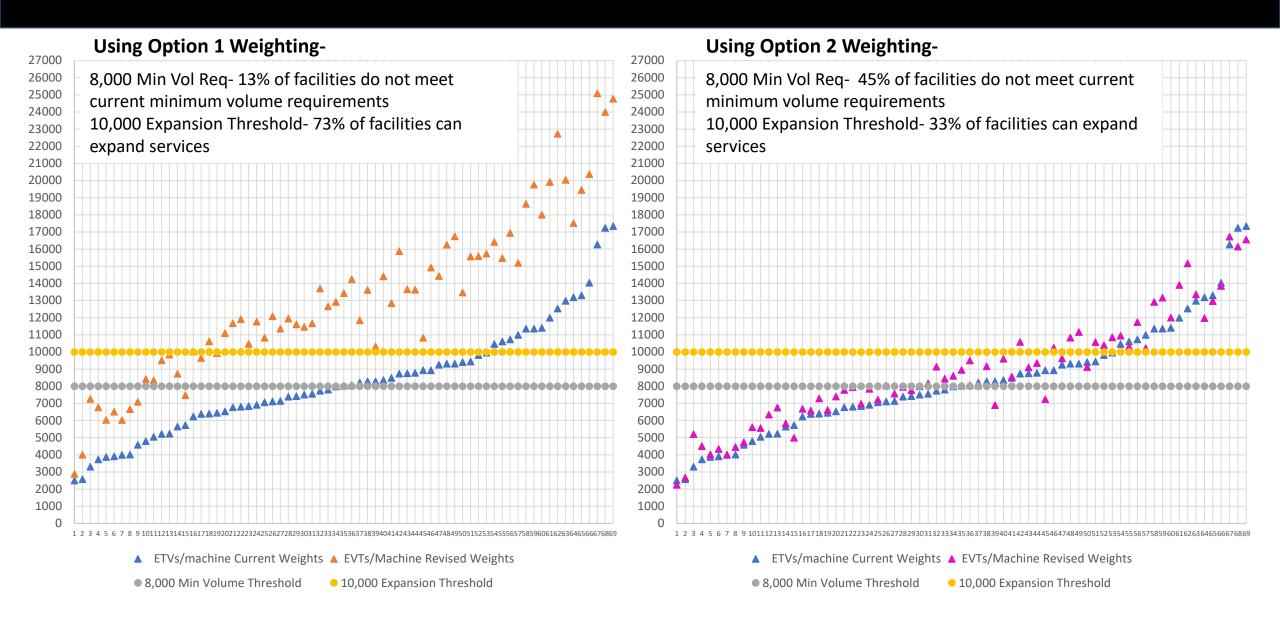
Recommended Weights Based on Typical Treatment Times

		Time for	Revised	Revised
		Typical	Weight	Weight
Treatment Visit Category	2016 Weight	Treatment	Option 1	Option 2
Simple*	1	10 min	1	0.66
Intermediate*	1.1	15 min	1.5	1
Complex**	1.25	30 min	3	2
IMRT**	2	25 min	2.5	1.66
Total Body Irradiation	8	75 min	7.5	5
HMRT Therapy	5		5	3.33
SRS/SBRT	8	45 min base	6	3
IORT	20		20	20
Additive Factors (Additional	weighting w	hen this techn	ology is appl	ied to any of
	the treatmen	nts above)		
Gating	+1	+15 min	+1	+1
			+2 per	+1.33 per
SRS/SBRT Additional		+20 min per	additional	additional
Isocenters		isocenter	isocenter	isocenter
MR-Guided Real Time				
Tracking w/o Adaptive		+30 min	+3	+2
MR-Guided Real Time				
Tracking Radiation WITH				
Adaptive		+45 min	+4.5	+3
		nine Time Use		
Patient Specific QA for iMRT		30 min	3.0	2.0
Patient Specific QA for				
SRS/SBRT		45 min	4.5	3.0
L	·			

Facility Performance by Machine Current Volume Requirements and Weighting

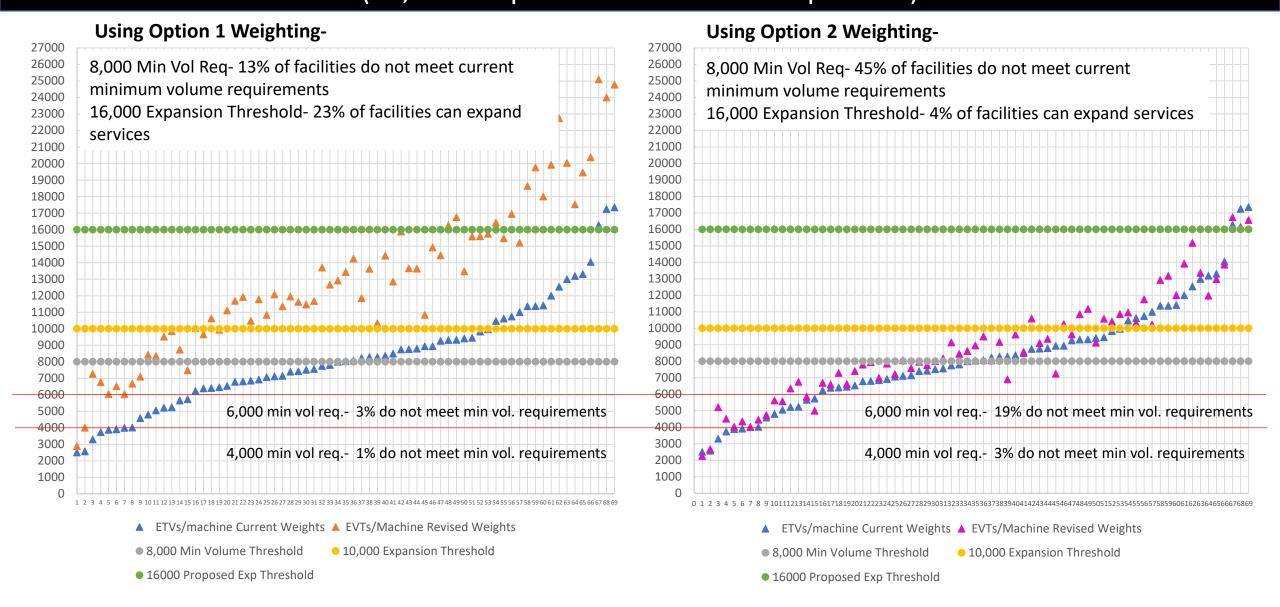


Facility Performance by Machine Current Volume Requirements, Current & Revised Weighting Options



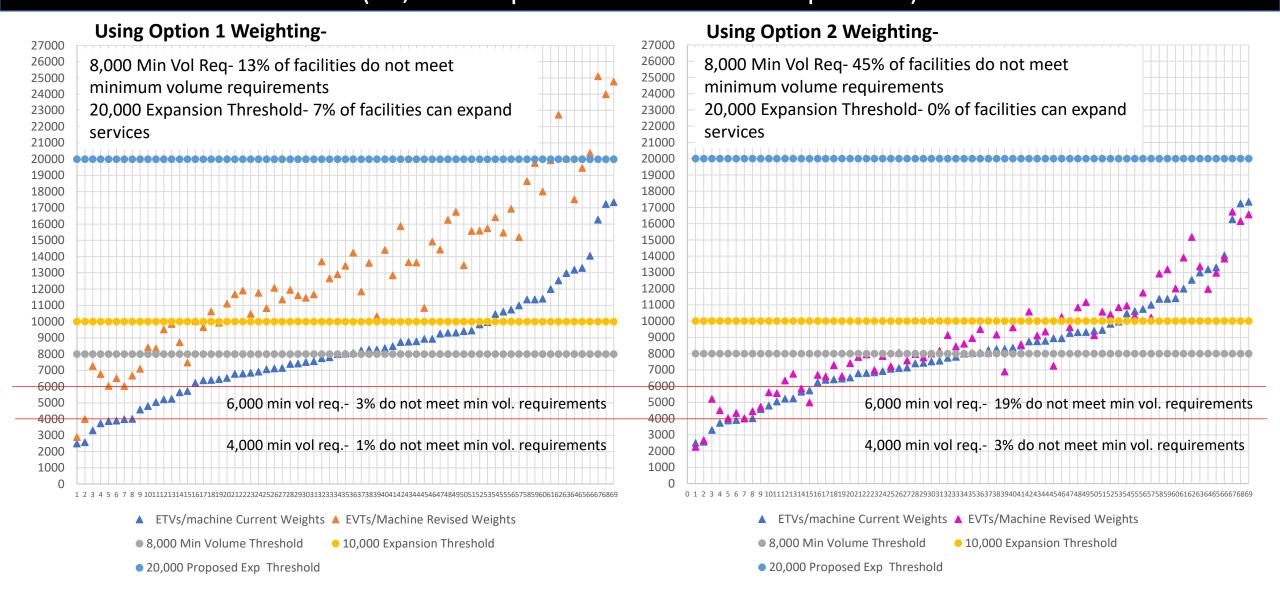
Facility Performance by Machine

Current Volume Requirements, Current ETV's Plus Suggested Weighting and Volume Options (16,000 Proposed Threshold for Expansion)



Facility Performance by Machine

Current Volume Requirements, Current ETV's Plus Suggested Weighting and Volume Options (20,000 Proposed Threshold for Expansion)



Summary of Analysis Revised Weightings and Potential Expansion Threshold Changes

	Current	Option 1	Option 2
	Weighting	Weighting	Weighting
Compliance with 8,000 Minimum	51%	87%	55%
	Compliant	Compliant	Compliant
	49%	13%	45%
	Not Compliant	Not Compliant	Not Compliant
Ability to Expand- 10,000 Threshold	23% Can Expand	73% Can Expand	33% Can Expand
Ability to Expand- 16,000 Threshold	0% Can Expand	23% Can Expand	4% Can Expand
Ability to Expand- 20,000 Threshold	0% Can Expand	7% Can Expand	0% Can Expand
Meeting Min Vol	22%	3%	19%
Req. 6,000	Not Compliant	Not Compliant	Not Compliant
Meeting Min Vol	10%	1%	3%
Req. 4,000	Not Compliant	Not Compliant	Not Compliant

		Time for Typical	Revised Weight	Revised Weight
Treatment Visit Category	2016 Weight	Treatment	Option 1	Option 2
Simple*	1	10 min	1	0.66
Intermediate*	1.1	15 min	1.5	1
Complex**	1.25	30 min	3	2
IMRT**	2	25 min	2.5	1.66
Total Body Irradiation	8	75 min	7.5	5
HMRT Therapy			5	3.33
SRS/SBRT		45 min base	6	3
IORT	20		20	20
Additive Factors (Additiona	al weighting v	when this tech	nology is ap	plied to any
	of the treatm	ents above)		
Gating	+1	+15 min	+1	+1
			+2 per	+1.33 per
SRS/SBRT Additional		+20 min per	additional	additional
Isocenters	NEW	isocenter	isocenter	isocenter
MR-Guided Real Time				
Tracking w/o Adaptive	NEW	+30 min	+3	+2
MR-Guided Real Time				
Tracking Radiation WITH				
Adaptive	NEW	+45 min	+4.5	+3
Ad	ditional Macl	hine Time Use		
Patient Specific QA for iMRT	NEW	30 min	3.0	2.0
Patient Specific QA for				
SRS/SBRT	NEW	45 min	4.5	3.0

Discussion, Thoughts, Questions



PATRICKS DONAN

Beaumont Health Public Comments Pertaining to MRT Services

MRT Standard Advisory Committee

August 30, 2018

Good morning. Beaumont Health appreciates the opportunity to provide comment on the MRT CON Review Standards.

We support the work of the Commission and the SAC to review this as this is their role, and believe that the current standards reasonably serve the needs of MI residents and communities. If the SAC decides to accept the weights as proposed at the July 26 meeting, all else equal this will result in markedly relaxed standards which will allow numerous MRT services to add non-special MRT units.

In comparing the current weights to the proposed weights based on 2017 data, the number of equivalent treatment visits (ETVs) for Beaumont's four MRT services would increase between 46% and 66%. In addition, while only one Beaumont MRT service would qualify for expansion under the current weights, all of them would qualify under the proposed weights.

Using the CON Annual Survey Data for MRT, we also analyzed at a sampling of 19 MRT services in Southeast Michigan (including Beaumont) and found similar results. For this sample the increase in ETVs using the proposed weights ranged from 23% to 79%. Furthermore, only two of the 19 services could expand under the current weights, however 17 of the 19 could expand under the proposed weights- clearly an unintended consequence.

If additional MRT units are approved due to new weights, this will predictably increase costs and could impact quality. If the SAC wants to consider changing the weights, we believe the SAC should undertake an analysis to determine how many additional linacs could be added across the State and the associated percentage increase in total capacity. The data to complete this analysis is on the CON website. Using the 2017 data on the CON website, the table below shows the average number of equivalent treatment visits (ETVs) by HSA:

HSA	ETV's	# MRT Units	ETV's per unit
HSA 1 – Southeast Michigan	533,138	63	8,463
HSA 2 - Mid-Southern	64,719	8	8,090
HSA 3 - Southwest	62,983	7	8,998
HSA 4 – West Michigan	108,746	11	9.886
HSA 5 – Genesee-Lapeer-Shiawassee	59,769	6	9,961
HSA 6 – East Central	66,997	10	6,700
HSA 7 – Northern Lower	49,382	6	8,230
HSA 8 – Upper Peninsula	13,940	2	6,970
Statewide Total	959,673	113	8,493

Note that for 6 of the 8 HSA's, and the Statewide Total, the average number of ETV's per unit is between the minimum compliance threshold (8,000 ETV's per unit) and the expansion threshold (10,000 ETV's per unit) This seems reasonable in that most services are at compliance and some qualify or nearly qualify for expansion based on their service utilization. For the two HSA's that have averages below the minimum threshold, one is the Upper Peninsula which may be appropriate due to access; and the other is East Central which has two facilities with less than half of the minimum volume threshold. Note also in Southeast Michigan, Beaumont had a freestanding MRT center in Southgate that was meeting less than half of the minimum volume threshold- which was closed earlier in 2018.

Finally, we note that the proposed MRT weights are based on "typical treatment times" that for some categories are significantly higher than what Beaumont's MRT services have experienced. See table below.

Treatment Visit Category	Beaumont Average Time for Treatment	MRT SAC Discussion Document "Typical Treatment Times"
Simple	12 mins	10 mins
Complex	17 mins	30 mins
IMRT	20 mins	25 mins
SBRT	36 mins	60 mins
Gating (Complex visit with gating)	22 mins	45 mins

Note: Treatment times vary for different categories based on patient mix

In summary, Beaumont believes the current system is working and recommends retaining the current weights and thresholds for the MRT CON Review Standards. Thank you.