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Department of Health and Mental Hygiene



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Health Services Cost Review Commission

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529th MEETING OF THE HEALTH SERVICES COST REVIEW COMMISSION
April 13, 2016

EXECUTIVE SESSION

11:00 a.m.

(The Commission will begin in public session at 11:00 a.m. for the purpose of, upon motion and approval, adjourning into closed session. The open session will resume at 2:00 p.m.)

1. **Update on Contract and Modeling of the All-payer Model vis-a-vis the All-Payer Model Contract – Administration of Model Moving into Phase II - Authority General Provisions Article, §3-103 and §3-104**
2. **Update on Hospital Rate Issue (JHH) - Authority General Provisions Article, §3-305 (7)**
3. **Discussion on Planning for Model Progression – Authority General Provisions Article, §3-103 and §3-104**

PUBLIC SESSION

2:00 p.m.

Review of the Minutes from the Public Meeting and Executive Session on March 9, 2016

1. **Executive Director's Report**
2. **New Model Monitoring**
3. **Docket Status – Cases Closed**

2317R – Holy Cross Health	2338A – Johns Hopkins Health System
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4. **Docket Status – Cases Open**

2319R – Sheppard Pratt Health System	2320N – Sheppard Pratt Health System
2337R – LifeBridge Health, Inc.	2339R – Prince George's Hospital Center
2340A – Johns Hopkins Health System	2341A – University of Maryland Medical Center
5. **Update Factor Discussion**
6. **Request by the Medical Assistance Program to Modify the Calculation of FY 2016 Current Financing Deposits**
7. **Draft Recommendation for NSPII**

- 8. Draft Recommendation for Continued Support of the Maryland Patient Safety Center**
- 9. Legal Report**
- 10. Legislative Update**
- 11. Hearing and Meeting Schedule**

Minutes to be included into the post-meeting packet
upon approval by the Commissioners

Executive Director's Report

The Executive Director's Report will be distributed during the Commission Meeting

New Model Monitoring Report

The Report will be distributed during the Commission Meeting

H.S.C.R.C's CURRENT LEGAL DOCKET STATUS (OPEN)

AS OF APRIL 5, 2016

A: PENDING LEGAL ACTION : NONE
 B: AWAITING FURTHER COMMISSION ACTION: NONE
 C: CURRENT CASES:

Docket Number	Hospital Name	Date Docketed	Decision Required by:	Rate Order Must be Issued by:	Purpose	Analyst's Initials	File Status
2319R	Sheppard Pratt Health System	11/24/2015	4/13/2016	4/22/2015	CAPITAL	GS	OPEN
2320N	Sheppard Pratt Health System	11/24/2015	4/13/2016	4/22/2015	OBV	DNP	OPEN
2337R	LifeBridge Health, Inc.	2/11/2016	4/13/2016	7/11/2016	Cancer Center	GS	OPEN
2339R	Prince George's Hospital Center	3/16/2016	4/15/2016	8/15/2016	PEDS/MSG	CK	OPEN
2340A	Johns Hopkins Health System	3/17/2016	N/A	N/A	ARM	DNP	OPEN
2341A	University of Maryland Medical Center	3/30/2016	N/A	N/A	ARM	DNP	OPEN

IN RE: THE PARTIAL RATE * BEFORE THE HEALTH SERVICES
APPLICATION OF * COST REVIEW COMMISSION
SHEPPARD PRATT * DOCKET: 2016
HOSPITAL * FOLIO: 2130
BALTIMORE, MARYLAND * PROCEEDING: 2320N

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Staff Recommendation

April 13, 2016

Introduction

On November 24, 2015, Sheppard Pratt Hospital (“SPH”) submitted a partial rate application to the Commission requesting a rate for a new Behavioral Observation Service (OBV). Since May of 2011, SPH has operated an outpatient walk-in-clinic (Clinic) for individuals in psychiatric crisis. The goal of the Clinic is to provide rapid evaluation for safety and referral to appropriate levels of care for individuals who could be safely assessed in a clinic setting and who do not have medical issues other than detoxification requiring transfer to a setting with more robust medical management capabilities, i.e., an Emergency Department (EMG). OBV will be used to treat a cohort of individuals presenting at SPH’s “walk-in-crisis” clinic (Clinic) seeking inpatient treatment for co-occurring disorders, i.e., a psychiatric diagnosis in combination with active substance use disorder. SPH has been unable to determine the appropriate treatment setting for these individuals because they are inebriated or under the influence of drugs. SPH intends to use the OBV to safely detoxify these individuals, in an observation status. Once the individual is competent to be evaluated, a psychiatric evaluation will be completed to determine if their psychiatric condition warrants inpatient admission or other treatment options.

SPH requests that the new rate of \$45.1358 be effective January 1, 2016.

Staff Findings

In its review, staff found that there have never been observation units in Maryland Private Psychiatric hospitals. Currently, individuals with co-occurring disorder that present at SPH are sent to an acute hospital Emergency Department where they are detoxified and psychiatrically evaluated. If they have a co-occurring disorder, they are referred back to SPH for treatment.

According to SPH, the new OBV service will save the Maryland health system money by avoiding the costs of transportation to an acute hospital emergency department and what are

typically extended emergency department visits. Savings would also be realized by reducing the inpatient length of stay for those individuals who require admission because they have already been detoxified within the OBV. In addition, SPH noted that a significant number of these individuals with co-occurring disorder are Medicaid recipients.

The Maryland Medicaid Program (MMP) commented on the application stating that it made programmatic sense. MMP also commented on SPH's proposed OBV rate. Noting that these patients are currently sent to an acute hospital Emergency Department, and then potentially to an OBV stay and then sent back to SPH for a mental health evaluation, SPH contends that the OBV rate would appear to be less expensive than the current practice.

The OBV rate requested by SPH of \$45.1358 is substantially lower than the OBV state-wide median rate of \$71.9972

Recommendation

After review of the application and analysis of the additional information provided by SPH and other sources, staff believes that the observation service for patients with co-occurring disorder requested by SPH will eliminate transfer to emergency departments, provide more efficient and effective patient care, and will save money for the Maryland health system.

Therefore, staff recommends that:

1. That an OBV rate of \$45.1358 per hour be approved effective April 1, 2016 for patients with co-occurring disorder only; and
2. That the OBV rate not be rate realigned until a full year's experience has been reported in SPH's Annual Report.

IN RE: THE PARTIAL RATE * BEFORE THE HEALTH SERVICES
APPLICATION OF * COST REVIEW COMMISSION
LIFEBRIDGE HEALTH, INC. * DOCKET: 2016
*** FOLIO: 2147**
BALTIMORE, MARYLAND * PROCEEDING: 2337R

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Staff Recommendation

April 13, 2016

Introduction

On February 1, 2016, LifeBridge Health, Inc. (the “System”) on behalf of Carroll Hospital Center (“Carroll”) and Sinai Hospital (“Sinai”) submitted a partial rate application to the Commission requesting that the rates of Carroll and Sinai be revised to reflect that the outpatient center at Carroll Hospital Cancer Center (“CHCC”) will operate as an off-site provider-based child-site of Sinai for purposes of the federal 340B program. The System requests that:

- 1) \$25.9 million be transferred from Carroll’s Total Patient Revenue (TPR) cap to Sinai’s Global Budget Revenue (GBR) cap, effective April 1, 2016;
- 2) The Commission approve new unit rates for CHCC services on Sinai’s rate order, effective April 1, 2016;
- 3) The Commission exclude the revenue for the new unit rates for CHCC services from rate realignment; and
- 4) The Commission adjust rate order volumes in Carroll’s and Sinai’s rate orders to maintain a neutral impact to rate capacity as a result of the request.

Maryland 2015 legislation (Senate Bill 513) altered the definition of “hospital services” to include hospital outpatient services of a hospital that is designated as part of another hospital under the same merged asset system to make it possible for the hospital outpatient services to participate in the federal 340B Prescription Drug Discount program.

In order to avail itself of the new legislation, the System requests that effective April 1, 2016 outpatient services provided at CHCC located on the Carroll campus be approved to begin operations as part of the Sinai Oncology program. The outpatient center located at CHCC will be able to operate as an off-site provider-based child-site of Sinai in accordance with Medicare’s

rules for provider-based status. As a result of this request, the child-site at CHCC will be able to participate in the 340B outpatient drug discount program under Sinai's eligibility. The savings generated through the 340B program at the child-site of approximately \$4.8 million will partially offset the 72% increase in drug costs at CHCC since 2012 which was not fully reflected in Carroll's TPR.

The System also requested that the rates approved on Sinai's rate order for the services provided at the CHCC child-site be those of CHCC for RY 2016. According to the application, savings of approximately \$200K will be generated for Medicare patients, who are currently 50.4% of patients at CHCC.

The System requests that the revision of rates and revenue between Carroll and Sinai be effective April 1, 2016.

Staff Findings

In its review, staff found that the revenue requested to be transferred from Carroll to Sinai, less the 340B savings remaining in Carroll's TPR revenue, appears to accurately reflect the annual revenue generated by CHCC. In addition, the rates and the revenue requested to be added to Sinai's Approved Rate Order and GBR are those approved by the HSCRC for RY 2016 for the CHCC services in Carroll's TPR.

Recommendation

After review of the application staff recommends that System's request be approved because: 1) it will enable Sinai to provide lower cost services to current oncology patients, and 2) it will generate future savings to the Maryland healthcare system and to additional oncology

patients through lower drug costs at the CHCC location.

Staff recommends that the approval be contingent upon Sinai applying for and receiving provider-based status from the Centers for Medicare and Medicaid Services for outpatient services provided at the CHCC site.

Staff also recommends that the following rates and the associated revenue for services provided at the CHCC location be approved and added to Sinai's approved rate order and GBR effective April 1, 2016:

1. A Clinic rate of \$41.70 per RVU;
2. A Radiology-Therapeutic rate of \$9.10 per RVU;
3. An OR Clinic rate of \$20.44 per minute;
4. A rebundled Laboratory rate of \$2.41 per RVU; and
5. Drug revenue of \$12,441,570.

**IN RE: THE APPLICATION FOR
ALTERNATIVE METHOD OF RATE
DETERMINATION ***

**JOHNS HOPKINS HEALTH
SYSTEM
BALTIMORE, MARYLAND**

*** BEFORE THE MARYLAND HEALTH
* SERVICES COST REVIEW
COMMISSION**

*** DOCKET: 2016**

*** FOLIO: 2150**

*** PROCEEDING: 2340A**



Staff Recommendation

April 13, 2016

I. INTRODUCTION

On March 17, 2016, the Johns Hopkins Health System (“System”) filed a renewal application on behalf of its member hospitals Johns Hopkins Hospital and Johns Hopkins Bayview Medical Center (the “Hospitals”) requesting approval from the HSCRC to continue to participate in a global rate arrangement for cardiovascular and joint procedures with Quality Health Management and to add pancreas and bariatric surgery procedures. The Hospitals request that the Commission approve the arrangement for one year effective May 1, 2016.

II. OVERVIEW OF APPLICATION

The contract will continue to be held and administered by Johns Hopkins HealthCare, LLC (“JHHC”), which is a subsidiary of the System. JHHC will continue to manage all financial transactions related to the global price contract including payments to the System hospitals and bear all risk relating to regulated services associated with the contract.

III. FEE DEVELOPMENT

The hospital portion of the global rates was developed by calculating mean historical charges for patients receiving the procedures for which global rates are to be paid. The remainder of the global rate is comprised of physician service costs. Additional per diem payments were calculated for cases that exceed a specific length of stay outlier threshold.

IV. IDENTIFICATION AND ASSESSMENT OF RISK

The Hospitals will continue to submit bills to JHHC for all contracted and covered services. JHHC is responsible for billing the payer, collecting payment, disbursing payments to the Hospitals at their full HSCRC approved rates, and reimbursing the physicians. The System contends that the arrangement among JHHC, the Hospitals, and the physicians holds the Hospitals harmless from any shortfalls in payment from the global price contract. JHHC maintains it has been active in similar types of fixed fee contracts for several years, and that JHHC is adequately capitalized to bear the risk of potential losses.

V. STAFF EVALUATION

Staff found that there was no activity under this arrangement for the last year. However,

staff believes that the Hospitals can achieve favorable performance under this arrangement.

VI. STAFF RECOMMENDATION

The staff recommends that the Commission approve the Hospitals' application for an alternative method of rate determination for cardiovascular, spine, pancreas, and bariatric surgery procedures for one year beginning May 1, 2016. The Hospitals must file a renewal application annually for continued participation.

Consistent with its policy paper regarding applications for alternative methods of rate determination, the staff recommends that this approval be contingent upon the execution of the standard Memorandum of Understanding ("MOU") with the Hospitals for the approved contract. This document will formalize the understanding between the Commission and the Hospitals, and will include provisions for such things as payments of HSCRC-approved rates, treatment of losses that may be attributed to the contract, quarterly and annual reporting, and confidentiality of data submitted, penalties for noncompliance, project termination and/or alteration, on-going monitoring, and other issues specific to the proposed contract. The MOU will also stipulate that operating losses under the contract cannot be used to justify future requests for rate increases.

**IN RE: THE APPLICATION FOR
ALTERNATIVE METHOD OF RATE
DETERMINATION**

**UNIVERSITY OF MARYLAND
MEDICAL CENTER
BALTIMORE, MARYLAND**

*** BEFORE THE MARYLAND HEALTH
* SERVICES COST REVIEW**

*** COMMISSION**

*** DOCKET: 2016**

*** FOLIO: 2151**

*** PROCEEDING: 2341A**

Staff Recommendation

April 13, 2016

I. INTRODUCTION

University of Maryland Medical Center (the Hospital) filed an application with the HSCRC on March 30, 2016 for an alternative method of rate determination, pursuant to COMAR 10.37.10.06. The Hospital requests approval from the HSCRC to continue to participate in a global rate arrangement for liver, kidney, lung, and blood and bone marrow transplants for a period of one year with Cigna Health Corporation beginning June 1, 2016.

II. OVERVIEW OF APPLICATION

The contract will continue be held and administered by University Physicians, Inc. ("UPI"), which is a subsidiary of the University of Maryland Medical System. UPI will manage all financial transactions related to the global price contract including payments to the Hospital and bear all risk relating to services associated with the contract.

III. FEE DEVELOPMENT

The hospital portion of the global rates was developed by calculating historical charges for patients receiving the procedures for which global rates are to be paid. The remainder of the global rate is comprised of physician service costs. Additional per diem payments were calculated for cases that exceed a specific length of stay outlier threshold.

IV. IDENTIFICATION AND ASSESSMENT OF RISK

The Hospital will continue submit bills to UPI for all contracted and covered services. UPI is responsible for billing the payer, collecting payments, disbursing payments to the Hospital at its full HSCRC approved rates, and reimbursing the physicians. The Hospital contends that the arrangement between UPI and the Hospital holds the Hospital harmless from any shortfalls in payment from the global price contract.

V. STAFF EVALUATION

The staff found that the Hospital's experience under this arrangement for the previous year was favorable.

VI. STAFF RECOMMENDATION

The staff recommends that the Commission approve the Hospital's application for an alternative method of rate determination for liver, kidney, lung, and blood and bone marrow transplant services, for a one year period commencing June 1, 2016. The Hospital will need to file a renewal application to be considered for continued participation.

Consistent with its policy paper regarding applications for alternative methods of rate determination, the staff recommends that this approval be contingent upon the execution of the standard Memorandum of Understanding ("MOU") with the Hospital for the approved contract. This document would formalize the understanding between the Commission and the Hospital, and would include provisions for such things as payments of HSCRC-approved rates, treatment of losses that may be attributed to the contract, quarterly and annual reporting, confidentiality of data submitted, penalties for noncompliance, project termination and/or alteration, on-going monitoring, and other issues specific to the proposed contract. The MOU will also stipulate that operating losses under the contract cannot be used to justify future requests for rate increases.

Update Factor Discussion

A presentation will be distributed at the Commission meeting

Staff Recommendation

Request by the Medical Assistance Program to Modify the Calculation
of Current Financing Deposits for CY 2016

April 13, 2016

Introduction

The Medical Assistance Program (MAP) has been providing working capital advance monies (current financing) to hospitals for many years. As a result, MAP receives the prompt pay discount as per COMAR 10.37.10.26(B). MAP is unique among third-party payers in that it is a governmentally funded program that covers qualified poor residents of Maryland. As such, it deals, to a large extent, with retroactive coverage. Recognizing the uniqueness of MAP, the Commission allowed MAP to negotiate a special formula with the hospital industry to calculate its fair share of current financing monies. The Commission approved this alternative method of calculating current financing at its February 1, 1995 public meeting. Currently, MAP has approximately \$95 million in current financing on deposit with Maryland hospitals.

As a result of the state budget crisis beginning in 2009, MAP requested, and the Commission approved exceptions to MAP's approved alternative method of current financing calculation. MAP also proposed that changes be made in its current financing formula when its new claims processing system, which was projected to achieve a dramatic reduction in hospital receivables, was implemented.

Status of MAP's New Claims Processing System

MAP reported that its new claims processing system, Medicaid Enterprise Restructuring Project, has been terminated, and that there is currently no timeline for implementing a new claims processing system.

MAP's Current Request

MAP has requested a continuation of the modified current financing formula be used for CY 2016, i.e., that the CY 2015 current financing deposits at each hospital be increased by the HSCRC's final update factor (2.61%). In addition, MAP requested that a workgroup be assembled to develop a revised methodology for calculating the current financing deposit.

Staff Recommendation

Since MAP's budget crisis appears to be subsiding, staff believes that MAP must again begin providing current financing working capital deposits that are appropriate for its population.

Therefore, staff recommends that the Commission approve MAP's request, but that the approval be contingent on MAP agreeing that the CY 2017 current financing deposits be calculated utilizing either a new permanent revised methodology developed by the work group, its currently approved alternative methodology, or the methodology utilized by all other third party payers.



Nurse Support Program II

Recommendations for the
FY 2017 NSP II Competitive Institutional Grants

HSCRC

Health Services Cost
Review Commission

FY 2016 - FY 2020: Updates

- ▶ NSP II Statute in Education Article, Section 11-405, revised to remove “bedside” as a descriptor.
- ▶ SB 208 voted favorable in both the House and Senate.
- ▶ Improved metrics and program evaluation process
- ▶ Developing enhancements to nursesupport.org website to provide automated data collection, management, analysis and reporting.

FY 2017 Grant Recommendations

- ▶ **Total Funding Recommended- \$17.5 mil**
 - ▶ 4 Planning Grants
 - ▶ 12 Implementation Grants
 - ▶ 3 Continuation Grants
- ▶ **Broad geographic representation**
- ▶ **Funding recommended for proposals at 11 higher education institutions**
 - ▶ 4 community colleges
 - ▶ 4 private
 - ▶ 2 public Universities
 - ▶ 1 HBCU

NURSE SUPPORT PROGRAM II
FY 2017 COMPETITIVE INSTITUTIONAL GRANTS

Health Services Cost Review Commission
4160 Patterson Avenue, Baltimore, MD 21215

DRAFT

April 13, 2016

This is a draft recommendation for Commission consideration at the April 13, 2016 Public Commission Meeting. Please submit comments on this draft to the Commission by Monday May 2nd, 2016, via hard copy mail or email to Oscar.Ibarra@maryland.gov.

Introduction

This report presents the recommendations of the Nurse Support Program II (NSP II) Competitive Institutional Grant Review Panel for FY 2017. The FY 2017 recommendations are in alignment with the NSP II goals and objectives as well as new recommendations at the national level. This report and recommendations are submitted by the Maryland Higher Education Commission (MHEC) and Health Services Cost Review Commission (HSCRC).

Background

Over the last 30 years, the Health Services Cost Review Commission has funded programs to address the cyclical nursing workforce shortages. In July 2001, the HSCRC implemented the hospital based NSP I program to address the nursing shortage impacting Maryland hospitals. On May 4, 2005, the HSCRC responded to the faculty shortage and limited nursing educational capacity underlying the nursing shortage with the NSP II. They approved an increase of 0.1% of regulated gross hospital revenue for use in expanding the pool of nurses in the state by increasing the capacity of nursing programs in Maryland through institutional and nursing faculty interventions. The Maryland Higher Education Commission (MHEC), the coordinating board for all Maryland institutions of higher education, was selected by the HSCRC to administer the NSP II programs.

The state of Maryland has made steady gains and much progress towards alleviating the state's nursing shortage. However, Maryland remains the only state in the geographic region and one of only sixteen (16) states in the nation projected to have a shortage of nurses in 2025 (HRSA, 2014). At the conclusion of the NSP II FY 2006 to FY 2015 program evaluation in

2015, the HSCRC renewed the funding for five additional years at 0.1% of hospital regulated gross patient revenue for FY 2016 through FY 2020.

Maryland Progress in Nursing Education

- Maryland has seen a 32% increase in entry level (BSN) and baccalaureate completion (RN-BSN) graduates from 1,105 BSN graduates in 2010 to 1,636 BSN graduates in 2015.
- The Associate Degree in Nursing (ADN) graduates increased 12% from 1,443 in 2010 to 1,625 in 2015.
- The Master's in Nursing (MSN) graduates increased from 441 in 2010 to 629 in 2015.
- The Nursing Practice and Research Doctoral (DNP and PhD) graduates increased from 64 in 2010 to 71 in 2015.

FY 2016- 2020 Updates

NSPII Program Improvements

The NSP II Statute in Education Article, Section 11-405 was reviewed with recommendations presented during the 2016 Maryland Legislative Session for the deletion of “bedside” as a descriptor for nurses. Instead of focusing on “bedside” nurses, SB 108 would allow the NSP II program to improve the pipeline of nurses with the skills necessary to keep pace with the rapidly changing provision of health care services. Steve Ports, Director, Center for Engagement and Alignment at the HSCRC testified as co-sponsor with Priscilla Moore, NSP II Grants Specialist at MHEC. SB 108 was voted favorable by the Maryland Senate voted on 2/3/16 and by the House on 3/15/16.

The most recent HSCRC recommendations to NSP II staff included focusing on better data management to inform future policy and programmatic decisions. In response to this

recommendation, enhancements to the existing nursesupport.org website are currently being developed to provide high volume data submission, management, analysis, and report preparation for future outcome evaluations. This project is on schedule to be completed in time for FY 2016- FY 2020 reporting.

New NSP II Programs: Academic and Practice Partnerships

The NSP II's newest programs, Nurse Leadership Consortium and Clinical Simulation Resource Consortium, align with the American Association of Colleges of Nursing-Manatt Report (2016); *Advancing Health Care Transformation: A New Era for Academic Nursing*. These new programs were created to provide opportunities across settings for academic nurse faculty and clinical practice nurses to work more closely together. Both programs have dedicated Advisory Councils with representation from hospitals and academia to provide oversight and guidance. During the first year, there were 72 registered nurse participants in the NSP II Leadership Consortium and Clinical Simulation Resource Consortium. These participants were nominated by health systems at nine (9) hospitals and twenty (20) nursing programs. These programs are open to all hospitals, health systems and schools of nursing through an annual nomination process.

FY 2017 Competitive Grant Process and Recommendations

In response to the FY 2017 RFA, the NSP II Competitive Institutional Grant Review Panel received twenty-four (24) new proposals and three (3) continuation recommendations. The seven-member review panel, comprised of hospital nursing educators, former NSP I and NSP II grant project directors, retired nurse educators, licensure and policy leaders along with MHEC and HSCRC staff, reviewed all proposals. All new proposals received by the deadline

were scored by the panel according to the rubric in the FY 2017 RFA. After the panel convened for full discussions, a consensus developed around the most highly recommended proposals. As a result, the committee agreed to recommend funding for sixteen (16) of the twenty-four (24) proposals. These funded proposals included planning grants of one (1) year to full implementation grants of five (5) years and three (3) continuation grants totaling \$17.5 mil. See Table 1 for a listing of the recommended grant awardees for FY 2017.

Table 1: Final Recommendations for funding for FY 2017 Competitive Institutional Grants

Grant #	Institution	Grant Title	Proposed Funding
17-102	CCBC	Expanded Pathways to BSN	\$1,085,971
17-104	Chesapeake College	Academic Progressions in Nursing	\$913,399
17-106	Hood College	Baccalaureate Nursing at Hood College	\$1,351,867
17-107	John Hopkins Univ.	Nurse Faculty for the Future	\$1,023,932
17-108	Morgan State Univ.	SAM II	\$784,438
17-110	Notre Dame	RN to BSN	\$1,716,608
17-112	Salisbury University	BS Bound	\$74,299
17-114	Stevenson University	Progress through Partnerships	\$1,363,848
17-115	University of Maryland	Care Coordination Specialty	\$255,198
17-116	University of Maryland	Care Coordination & Case Management	\$113,701
17-117	University of Maryland	Collaborative NP Clinical Training	\$945,866
17-119	University of Maryland	Developing Educators to Teach Online	\$80,970
17-120	University of Maryland	Faculty Mentorship Program II	\$350,031
17-121	University of Maryland	FNP Expansion to Shady Grove	\$1,586,781
17-123	University of Maryland	Project RUSH- PhD Program	\$595,210
17-124	University of Maryland	Psychiatric MH FNP	\$168,924
17-125	John Hopkins Univ.	Inter-professional Education	\$1,692,335
17-126	University of Maryland	RN- BSN or MSN Clinical Faculty	\$3,120,506
17-127	Montgomery College	Military to Associate Degree	\$341,594

TOTAL \$17, 565,478

The funded proposals were representative of the commitment of NSP II to nursing degree completions, seamless academic pathways, academic practice partnerships, increasing diversity, and statewide resources. The most highly recommended proposals supported nursing undergraduate degree completions at Morgan State University, Associate to Bachelor degrees at

The Community College of Baltimore County, RN-BSN completion programs at Notre Dame of Maryland University and Stevenson University, along with two Care Coordination and Case Management planning grants at the University of Maryland. The final recommended proposals align with the NSP II goals and support nursing education across the Maryland.

The HSCRC and MHEC staff members are recommending that the NSP II Competitive Institutional Grant Review Panel recommendations are approved for FY 2017 funding as presented, to become effective on July 1, 2016.

References

American Association of Colleges of Nursing- Manatt (2016). *Advancing Health Care Transformation: A New Era for Academic Nursing*. Accessed on March 30, 2016 at <http://www.aacn.nche.edu/AACN-Manatt-Report.pdf>

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Nurse Support Program II (NSP II) Outcomes Evaluation FY 2006 – FY 2015, Health Services Cost Review Commission, January 14, 2015 Minutes. <http://www.hscrc.state.md.us/documents/commission-meeting/2015/01-14/HSCRC-Post-Commission-Meeting-2015-01-15.pdf>

U.S. Department of Health and Human Services, Health Resources and Services Administration, National Center for Health Workforce Analysis. *The Future of the Nursing Workforce: National- and State-Level Projections, 2012-2025*. Rockville, Maryland, 2014. <http://bhw.hrsa.gov/healthworkforce/supplydemand/nursing/workforceprojections/nursingprojections.pdf>

**Draft Recommendations on Continued Financial Support of the
Maryland Patient Safety Center for FY 2017**

**Draft Recommendations on Continued
Financial Support for the Maryland Patient
Safety Center for FY 2017**

April 6, 2016

**Health Services Cost Review Commission
4160 Patterson Avenue
Baltimore, MD 21215**

This document contains the draft staff recommendations for providing continued financial support of the Maryland Patient Safety Center. Comments on this draft may be submitted via hard copy or email to Dianne Feeney at Dianne.feeney@maryland.gov by COB April 29, 2016.

Draft Recommendations on Continued Financial Support of the Maryland Patient Safety Center for FY 2017

Introduction

In 2004, the HSCRC adopted recommendations that made it a partner in the initiation of the Maryland Patient Safety Center (MPSC) by providing seed funding through hospital rates. The initial recommendations provided funding to cover 50% of the reasonable budgeted costs of the Center. The Commission works collaboratively on MPSC projects as appropriate, and receives a briefing and documentation annually on the progress of the MPSC in meeting its goals as well as an estimate of expected expenditures and revenues for the upcoming fiscal year. Based on staff project collaboration experience, and on the annual information provided by MPSC, staff evaluates the reasonableness of the budget items presented and makes continued financial support recommendations to the Commission.

Over the past 12 years, the rates of eight Maryland hospitals were increased by the following amounts in total, and funds have been transferred on a biannual basis (by October 31 and March 31 of each year):

- FY 2005 - \$ 762,500
- FY 2006 - \$ 963,100
- FY 2007 - \$1,134,980
- FY 2008 - \$1,134,110
- FY 2009 - \$1,927,927
- FY 2010 - \$1,636,325
- FY 2011 - \$1,544,594
- FY 2012 - \$1,314,433
- FY 2013 - \$1,225,637
- FY 2014 - \$1,200,000
- FY 2015 - \$1,080,000
- FY 2016 - \$972,000

In March 2016, the HSCRC received the attached request for continued financial support of the MPSC through hospital rates in FY 2017 (Appendix I). The MPSC is requesting a total of \$874,800 in funding support from HSCRC, a decrease of 10% from the previous year.

Background

The 2001 General Assembly passed the “Patients’ Safety Act of 2001,” charging the Maryland Health Care Commission (MHCC), in consultation with the Department of Health and Mental Hygiene (DHMH), with studying the feasibility of developing a system for reducing the number of preventable adverse medical events in Maryland including, a system of reporting such incidences. The MHCC subsequently

Draft Recommendations on Continued Financial Support of the Maryland Patient Safety Center for FY 2017

recommended the establishment of a Maryland Patient Safety Center (MPSC or Center) as one approach to improving patient safety in Maryland.

In 2003, the General Assembly endorsed this concept by including a provision in legislation to allow the MPSC to have medical review committee status, thereby making the proceedings, records, and files of the MPSC confidential and not discoverable or admissible as evidence in any civil action.

The MHCC selected the Maryland Hospital Association (MHA) and the Delmarva Foundation for Medical Care (Delmarva or DFMC) through the State of Maryland's Request for Proposals (RFP) procurement process to establish and begin operating the MPSC in 2004, with an agreement that the two organizations would collaborate in their efforts. MHA and Delmarva jointly operated the Center from 2004 to 2009. The Center was then reorganized as an entity independent from MHA and DFMC, and re-designated by MHCC as the state's patient safety center starting in 2010 for two additional five-year periods; the Center's current designation extends through December 2019.

Assessment

Strategic Priorities and Partnerships

MPSC's vision is to be a center of patient safety innovation, convening providers of care to accelerate understanding of, and implement evidence-based solutions for, preventing avoidable harm. Its stated mission is make healthcare in Maryland the safest in the nation

The Center's goals are to:

- Eliminate preventable harm for every patient, with every touch, every time
- Develop a shared culture of safety among patient care providers
- Be a model for safety innovation in other states

To accomplish its vision, mission and goals, the MPSC has established and continues to build new strategic partnerships with an array of key private and public organizations. The organizations represent a broad array of interests and expertise including policymakers, providers of care across the continuum of, healthcare quality/safety, and healthcare learning and education.

Appendix I more fully details the Center's priorities and partnerships.

Maryland Patient Safety Center Activities, Accomplishments, and Outcomes

The highlights of the Center's key accomplishments for FY 2016, more fully outlined in Appendix I, include:

- Member hospitals totaled 43

Draft Recommendations on Continued Financial Support of the Maryland Patient Safety Center for FY 2017

- Began marketing of Caring for the Caregiver with strong interest from hospitals in Maryland, NY, SC, and CA.
- Mid-Atlantic PSO members include 26 facilities
- Commenced First Time Cesarean-Section initiative
- Commenced Neonatal Abstinence Syndrome initiative
- Recruited 16 hospitals, 5 LTC and 5 ASC's for Clean Collaborative initiative- Recruitment continues.
- Sepsis Collaborative improvements to date show Cohort I has decreased sepsis mortality in by 11.0% and Cohort II by 11.1%
- Partnered with VHQC in a LTC Sepsis collaborative (32 MD LTCs)
- Safe from Falls- LTC collaborative completed and decreased falls with injury in participating long term care facilities by 30.56%

For FY 17, the Center is conducting the activities outlined below (also see Appendix I).

- Perinatal/Neonatal Quality Collaborative

Reduce first time C-sections in singleton, vertex, nulliparous women (readmissions, LOS)

Standardizing care and treatment of neonatal abstinence syndrome (readmissions, LOS, transfers to higher levels of care)

- Sepsis Prevention (LTC)

Partnering with VHQC to reduce mortality in the post acute setting (readmissions, LOS)

- Sepsis Mortality (acute care)

Reduce mortality due to sepsis through early identification and rapid treatment (LOS, mortality)

- Clean Collaborative

Reduce incidence of HAI's through improved practices related to surface contamination (PPC's, LOS)

- Errors in Diagnosis

Convene study group to analyze IOM September 2015 recommendations for adoption and development of statewide initiative (LOS, readmissions, utilization)

- Patient Family Centered Care Bundle

Convene study group to institute relevant patient family centered care related activities (readmissions, patient satisfaction)

- Medication Reconciliation

Convene study group to develop applicable initiative(s) (readmissions, LOS)

FY 2017 Projected Budget

MPSC continued its efforts to work with its partners to secure program-specific funding for FY 2017, and estimates the amounts they will secure for FY 2017 in the proposed budget outlined in Figure 1 below.

**Draft Recommendations on Continued Financial Support of the
Maryland Patient Safety Center for FY 2017**

Figure 1. Proposed Revenue and Expenses

REVENUE	FY 2016 Budget			FY 2017 Budget		
Cash Contributions from MHA/Delmarva			100,000			100,000
Cash Contributions from Hospitals			75,000			30,000
Cash Contributions for Long-term Care			25,000			25,000
HSCRC Funding			972,000			874,800
Membership Dues			275,000			350,000
Education Session Revenue			22,000			14,000
Conference Registrations-Annual MedSafe Conference			3,000			2,000
Conference Registrations-Annual Patient Safety Conference			130,000			75,000
Sponsorships			130,000			140,000
Program Sales			60,000			60,000
Patient Safety Certification Revenue			-			85,000
DHMH Grant			200,000			200,000
Other Grants/Contributions			100,000			50,000
Total Revenue			2,092,000			2,005,800
EXPENSES	FY 2016 MPSC	FY 2016 Consultants	FY 2016 Total	FY 2017 MPSC	FY 2017 Consultants	FY 2017 Total
Administration	551,250		551,250	581,750		581,750
Outpatient Dialysis (previously committed)	-		-	-		-
Programs			-			-
Education Sessions		78,000	78,000		69,000	69,000
Annual Patient Safety Conference		360,000	360,000		370,500	370,500

**Draft Recommendations on Continued Financial Support of the
Maryland Patient Safety Center for FY 2017**

MEDSAFE Conference		55,000	55,000		33,250	33,250
Caring for HC Patient/Family Centered Care	57,000	60,000	117,000	93,400	50,000	143,400
	-	-	-	-	-	-
Safety Initiatives-Perinatal/Neonatal	221,300	-	221,300	206,850	-	206,850
Safety Initiatives-Hand Hygiene	52,050	15,000	67,050	-	-	-
Safety Initiatives-Safe from Falls	24,600	500	25,100	-	-	-
Safety Initiatives-Adverse Event Reporting	15,600	85,000	100,600	25,100	40,000	65,100
Patient Safety Certification	117,400	52,000	169,400	132,300	15,000	147,300
Sepsis	71,500	87,900	159,400	38,200	47,150	85,350
Clean Environment	81,600	105,000	186,600	61,300	97,900	159,200
Patient Family Bundle				22,700	-	22,700
Med Rec				19,500	-	19,500
Surgical				19,500	-	19,500
Diagnosis Errors				19,500	-	19,500
Total Expenses	1,192,300	898,400	2,090,700	1,220,100	722,800	1,942,900
Net Income (Loss)			<u>1,300</u>			<u>62,900</u>

Draft Recommendations on Continued Financial Support of the Maryland Patient Safety Center for FY 2017

MPSC Return on Investment

As was noted in the last several Commission recommendations, the All-Payer System has provides funding support for the Maryland Patient Safety Center with the expectation that there would be both short-term and long-term reductions in Maryland healthcare costs – particularly related to such outcomes as reduced mortality rates, lengths of stays, patient acuity, and malpractice insurance costs. However, these results continue to be difficult to quantify and the Center has been able to provide limited evidence that the programs have resulted in cost savings, and only to the extent that these savings relate to individual programs and for limited periods of time.

Based on the data that is generated and reported by MPSC to HSCRC (e.g., 11% reduction in sepsis mortality in cohorts I and II), staff continues to believe there are indications that the programs of the MPSC are well conceived. The sepsis early identification and mortality reduction program aligns with the Commission’s goals as it aspires to reduce infection complications and mortality. MPSC has continued to work to maintain sources of revenue, e.g., in conference registration fees and in membership dues, demonstrating perceived value of the Center’s provider customer base.

Recommendations

In light of the information presented above, staff provides the following draft recommendations on the MPSC funding support policy:

1. HSCRC provide funding support for the MPSC in FY 2017 through an increase in hospital rates in the amount of \$874,800 a \$97,200 (10%) reduction from FY 2016;
2. The MPSC continue to aggressively pursue other sources of revenue, including from other provider groups that benefit from the programs of the Center, to help support the Center into the future, and maintain reasonable cash reserves;
3. Going forward, HSCRC continue to decrease the dollar amount of support by a minimum of 10% per year, or a greater amount contingent upon:
 - a. how well the MPSC initiatives fit into and line up with a broader statewide plan and activities for patient safety; and
 - b. whether new MPSC revenues should offset HSCRC funding support.

Maryland Patient Safety Center FY 2017 Program Plan & Budget

Presented to the
Health Services Cost Review
Commission
March 2016



**Appendix I: MPSC Report to HSCRC on FY 2015 Results and
FY 2016 Program Plan and Budget Request**

Maryland Patient Safety Center Board of Directors

- **James R. Rost, MD**, Medical Director, NICU and Medical Director of Patient Safety, Shady Grove Adventist Hospital
- **Gerald Abrams**, Director
Abrams, Foster, Nole & Williams, PA
- **Carmela Coyle**, President & CEO
Maryland Hospital Association
- **Joseph DeMattos, Jr., MA**, President
Health Facilities Association of Maryland
- **Deborah Dokken**
Patient / Family Advocate
- **Barbara Epke**, Vice President
LifeBridge Health, Inc. & Sinai Hospital of Baltimore
- **E. Robert Feroli, Jr., PharmD, FASHP, FSMSO**
Johns Hopkins Hospital, Department of Pharmacy
- **Eugene Friedman**, Former Corporate Counsel
1st Mariner Bank
- **Paul Fronstin, Ph.D.**, Director, Center for Research and Health Benefits Innovation, Employee Benefit Research Institute;
Commissioner, Maryland Health Care Commission
- **Warren Green**, Former President & CEO
LifeBridge Health
- **David Horrocks**, President, CRISP
- **Andrea Hyatt**, President, Maryland Ambulatory Surgery Association
- **Robert Imhoff**, President & CEO
Maryland Patient Safety Center
- **Joanna Kaufman**, Former Program/Information Specialist, Institute for Patient- and Family-Centered Care
- **Lawrence Linder, MD, FACEP, FAAEM**
President and CEO
University of Maryland Community Medical Group
- **David Mayer, MD**
Corporate Vice President of Quality and Safety
MedStar Health
- **Sherry Perkins, PhD, RN**, COO and CNO
Dimensions Health
- **Steve Ports**, Principal Deputy Director
Health Services Cost Review Commission
- **Sheree Sample-Hughes**, Delegate, Maryland General Assembly, District 37 A
- **Susan Sheridan**, Patient / Family Advocate
- **Barbara Tachovsky**, Former President, Main Line Hospitals, Paoli, PA.
- **Kathleen White, PhD, RN, NEA-BC, FAAN**,
Associate Professor
Department of Acute and Chronic Care
The Johns Hopkins University
School of Nursing



Strategic Priorities

Vision - *Who we are*

A center of patient safety innovation, convening providers of care to accelerate our understanding of, and implement evidence-based solutions for, preventing avoidable harm

Mission – *Why we exist*
Making healthcare in Maryland the safest in the nation

Goals - *What will we accomplish*

- Eliminate preventable harm for every patient, with every touch, every time
- Develop a shared culture of safety among patient care providers
- Be a model for safety innovation in other states

Strategic Areas of Focus - *What we will do*

Prevent Harm and Demonstrate the Value of Safety

Spread Excellence

Lead Innovation in New Areas of Safety Improvement



Appendix I: MPSC Report to HSCRC on FY 2015 Results and FY 2016 Program Plan and Budget Request

Strategic Partners

- **Courtemanche & Associates** - An interdisciplinary healthcare firm that serves healthcare organizations to improve care through compliance with regulatory and accreditation requirements
- **Quantros** - National vendor of adverse event reporting services
- **VHQC** – Maryland QIO
- **Vermont Oxford Network** - Voluntary collaboration of healthcare professionals working together as an interdisciplinary community to change the landscape of neonatal care.
- **American College of Obstetrics and Gynecologists** - national organization promoting maternal and infant health
- **Health Facilities Association of Maryland** - A leader and advocate for Maryland's long-term care provider community
- **Institute for Safe Medication Practices** – The leading national organization educating others about safe medication practices
- **Maryland Healthcare Education Institute** – The educational affiliate of the Maryland Hospital Association
- **Maryland Hospital Association** - The advocate for Maryland's hospitals, health systems, communities, and patients before legislative and regulatory bodies
- **LifeSpan Network** - The largest senior care provider association in the Mid-Atlantic, representing more than 300 senior care provider organizations in Maryland and the District of Columbia
- **Maryland Ambulatory Surgical Association** - The state membership association that represents ambulatory surgery centers (ASCs) and provides advocacy and resources to assist ASCs in delivering high quality, cost-effective ambulatory surgery to the patients they serve
- **Johns Hopkins School of Medicine / The Armstrong Institute for Patient Safety and Quality** – The patient safety center within Johns Hopkins Medicine



FY16 Highlights

- Began marketing of Caring for the Caregiver with strong interest from hospitals in Maryland, NY, SC, and CA.
- Member hospitals totaled 43
- Mid-Atlantic PSO members include 26 facilities
- Commenced First Time Cesarean-Section initiative
- Commenced Neonatal Abstinence Syndrome initiative
- Recruited 16 hospitals, 5 LTC and 5 ASC's for Clean Collaborative initiative. Recruitment continues.
- Sepsis Collaborative improvements to date show Cohort I has decreased sepsis mortality in by 11.0% and Cohort II by 11.1%
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- Safe from Falls- LTC collaborative completed and decreased falls with injury in participating long term care facilities by 30.56%

Appendix I: MPSC Report to HSCRC on FY 2015 Results and
FY 2016 Program Plan and Budget Request

FY17 Initiatives: Safety Initiatives

- **Perinatal/Neonatal Quality Collaborative**
 - Reduce first time C-sections in singleton, vertex, nulliparous women (readmissions, LOS)
 - Standardizing care and treatment of neonatal abstinence syndrome (readmissions, LOS, transfers to higher levels of care)
- **Sepsis Prevention (LTC)**
 - Partnering with VHQC to reduce mortality in the post acute setting (readmissions, LOS)
- **Sepsis Mortality (acute care)**
 - Reduce mortality due to sepsis through early identification and rapid treatment (LOS, mortality)
- **Clean Collaborative**
 - Reduce incidence of HAI's through improved practices related to surface contamination (PPC's, LOS)
- **Errors in Diagnosis**
 - Convene study group to analyze IOM September 2015 recommendations for adoption and development of statewide initiative (LOS, readmissions, utilization)
- **Patient Family Centered Care Bundle**
 - Convene study group to institute relevant patient family centered care related activities (readmissions, patient satisfaction)
- **Medication Reconciliation**
 - Convene study group to develop applicable initiative(s) (readmissions, LOS)



FY17 Initiatives: Education Programs

- Educational programming according to needs of members & marketplace.
- Objectives:
 - Educate providers regarding pertinent patient safety/medication related issues
 - Expand geographic and participant reach of the Center
 - Increase participation levels
 - Increase revenue generation
 - Establish Center as recognized educational resource



FY17 Initiatives: Conferences

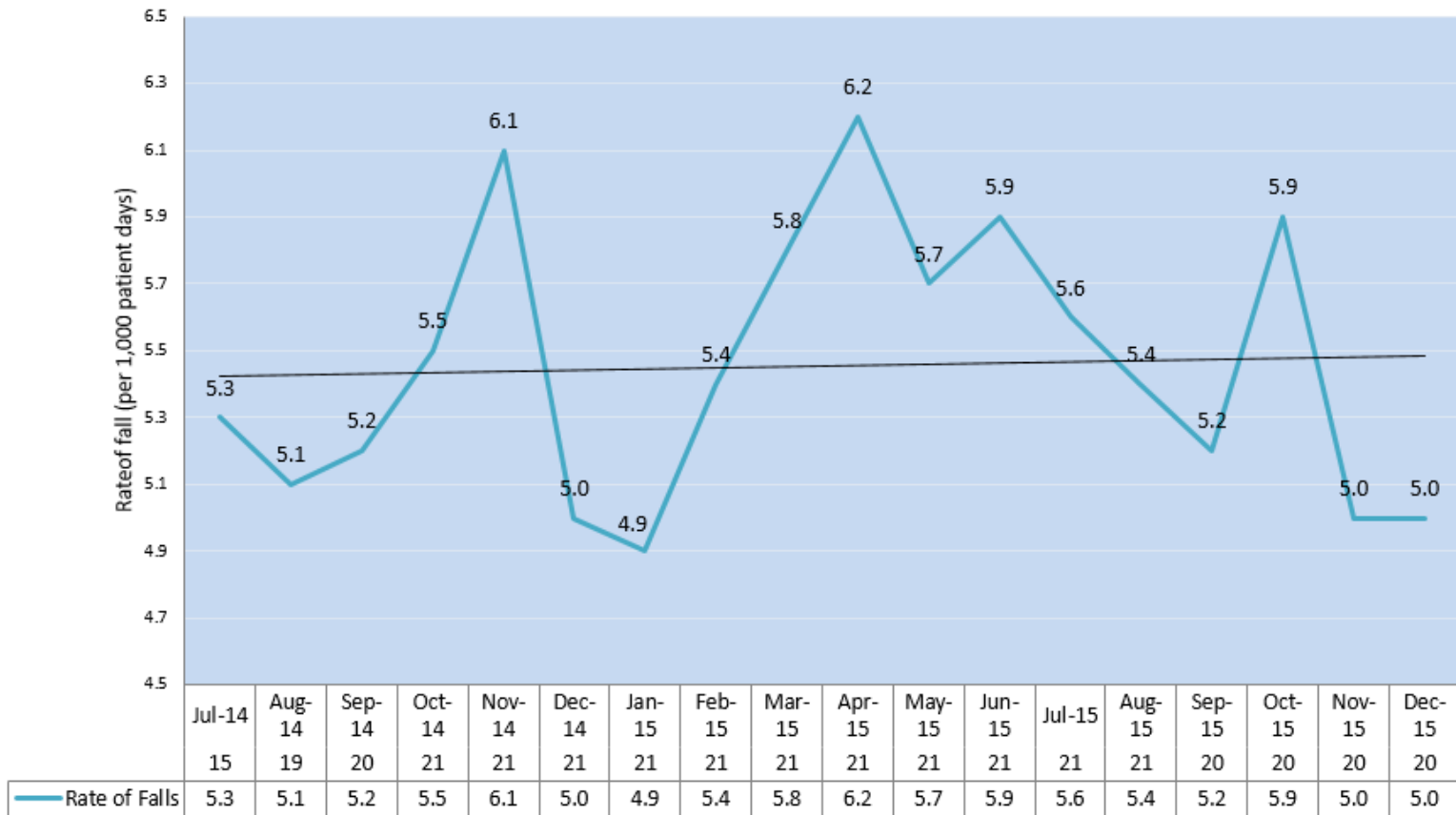
- The Annual Maryland Patient Safety Center Conference is the Center's signature event; providing awareness, education and the exchange of best practice solutions to a broad-based audience that goes well beyond the Center's usual participants. The annual Medication Safety Conference has become a premier event for the Center concentrating on the prevention of medication errors with an emphasis on processes and technology.
- Objectives:
 - Educate providers regarding pertinent patient safety / medication related issues
 - Expand geographic and participant reach of the Center
 - Increase participation levels
 - Increase revenue generation
 - Establish Center as recognized educational resource
- Vendor: Maryland Healthcare Education Institute



Appendix I: MPSC Report to HSCRC on FY 2015 Results and
 FY 2016 Program Plan and Budget Request

SAFE from FALLS – Long Term Care

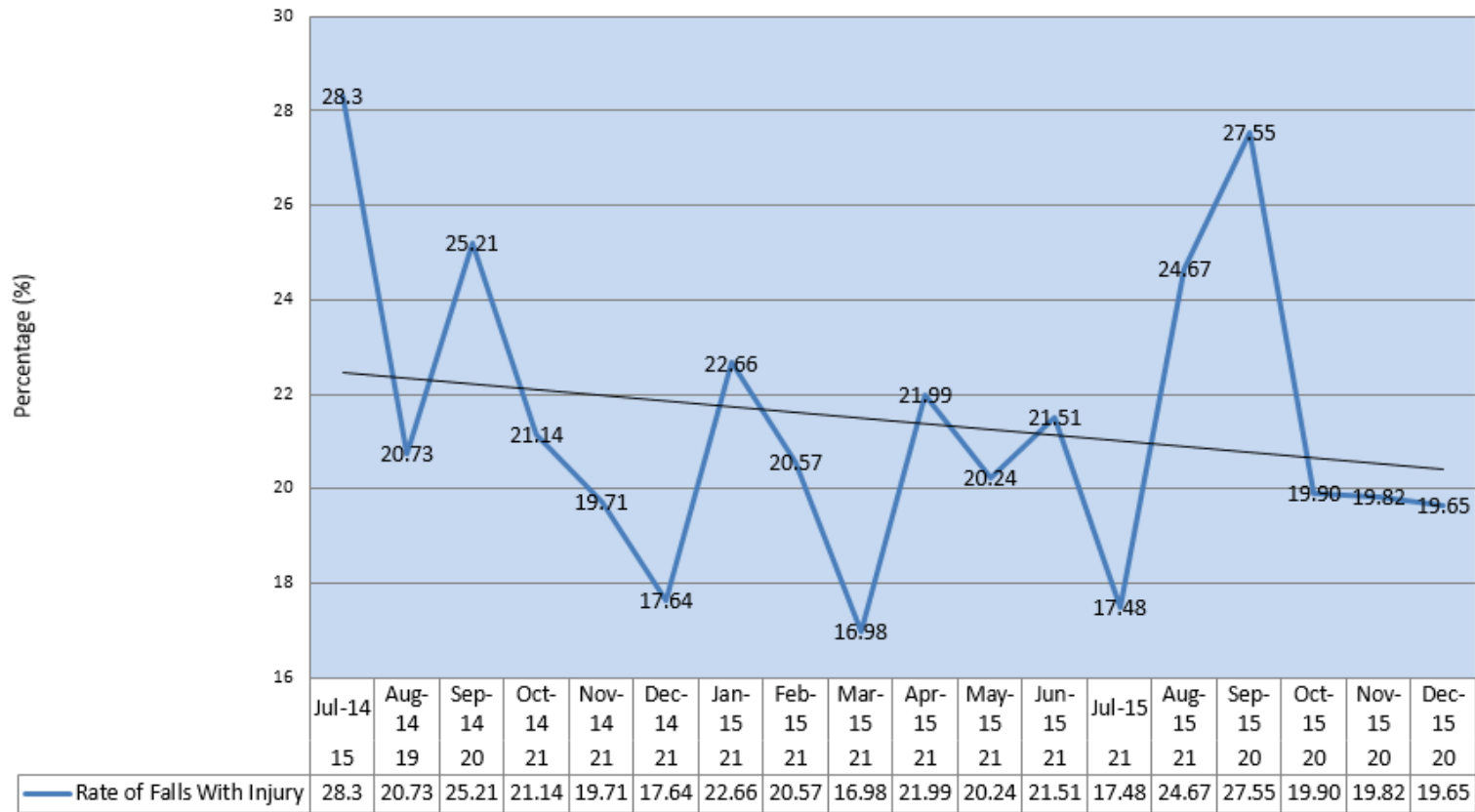
Long Term Care Rate of Falls in Participating Facilities
 July 2014 to December 2015



**Appendix I: MPSC Report to HSCRC on FY 2015 Results and
FY 2016 Program Plan and Budget Request**

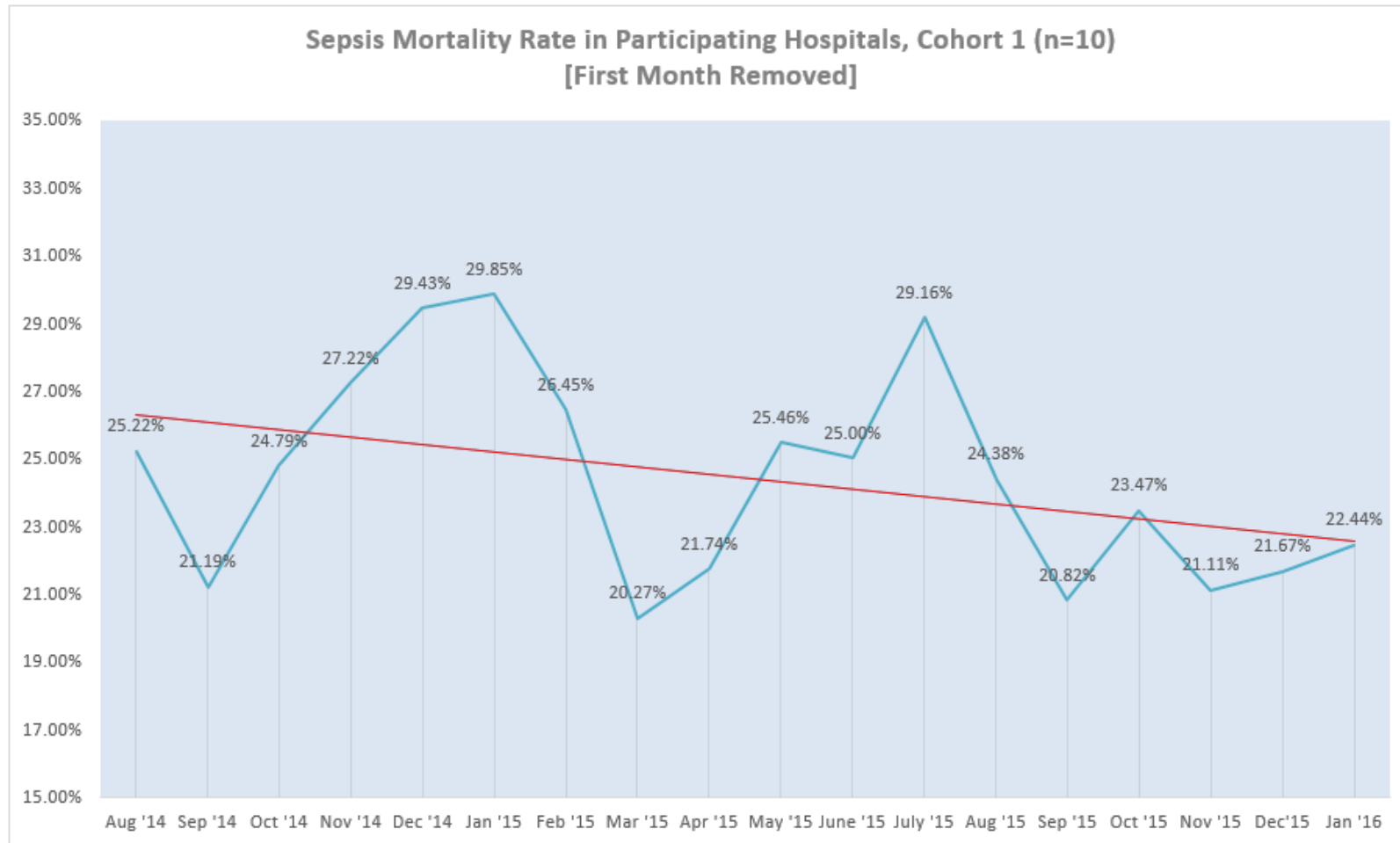
SAFE from FALLS – Long Term Care

**Rate of Falls with Injury in Participating Facilities
July 2014 to December 2015**



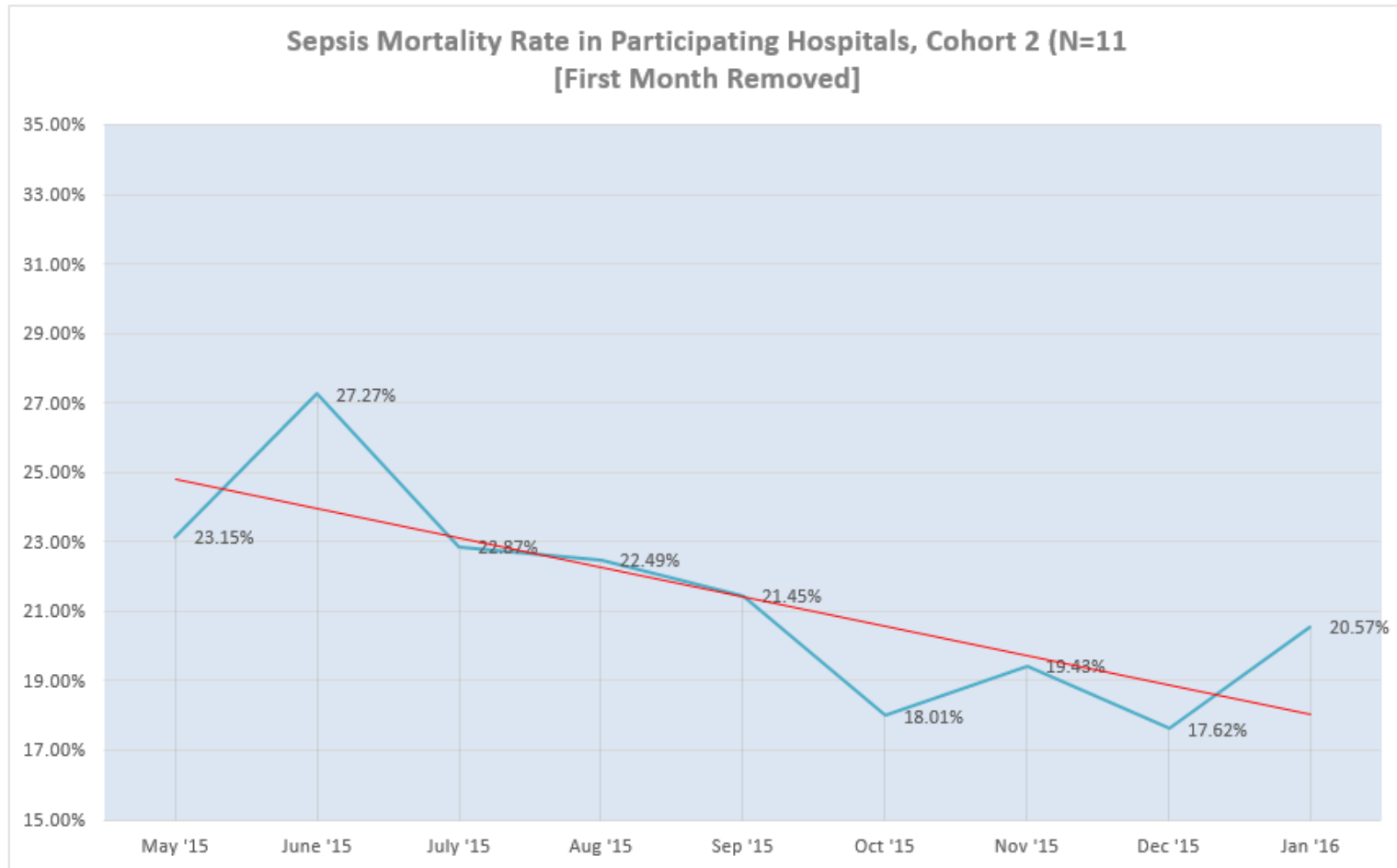
Appendix I: MPSC Report to HSCRC on FY 2015 Results and
FY 2016 Program Plan and Budget Request

Improving Sepsis Mortality



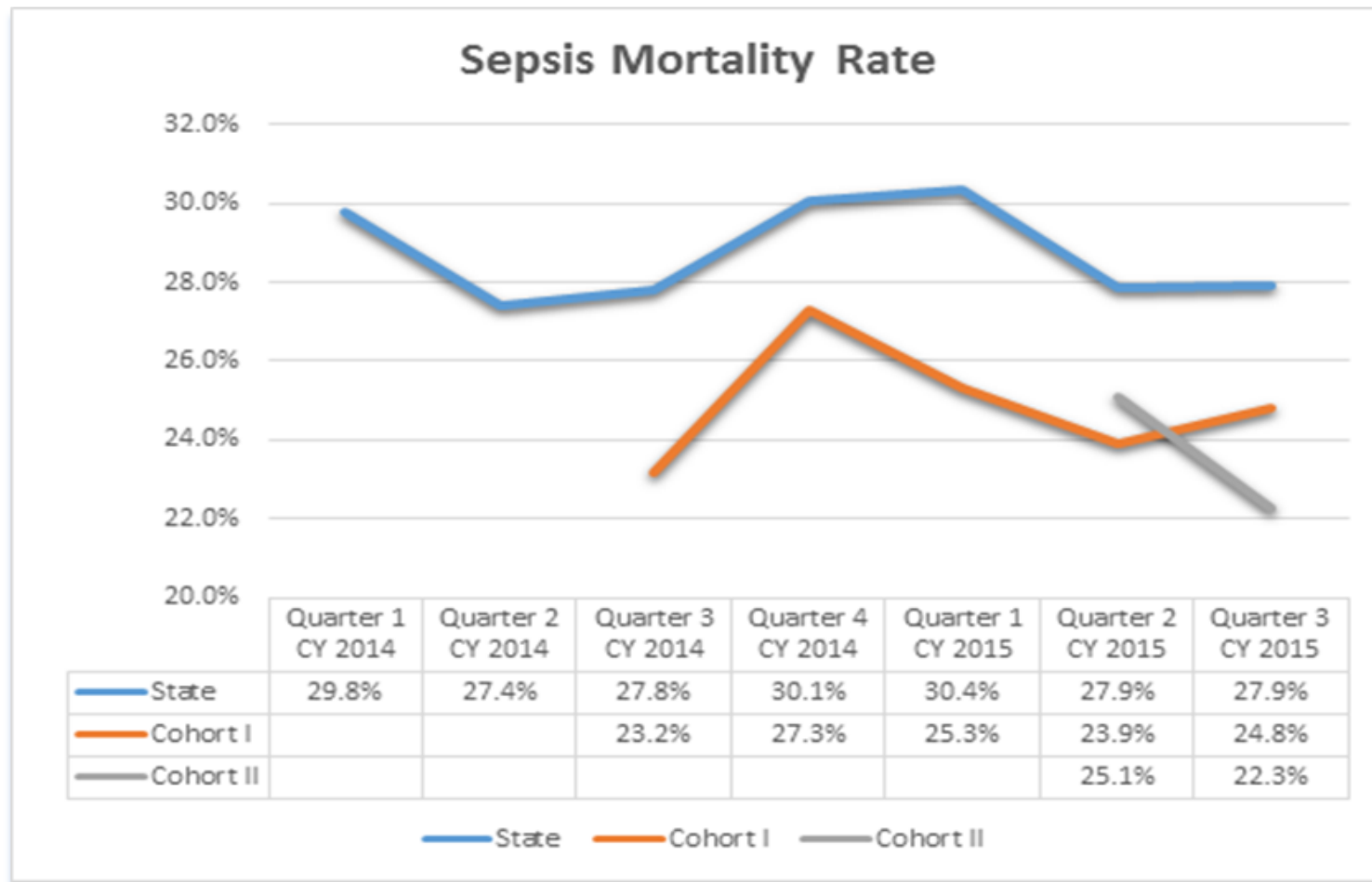
Appendix I: MPSC Report to HSCRC on FY 2015 Results and
FY 2016 Program Plan and Budget Request

Improving Sepsis Mortality



Appendix I: MPSC Report to HSCRC on FY 2015 Results and
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Improving Sepsis Mortality



**Appendix I: MPSC Report to HSCRC on FY 2015 Results and
FY 2016 Program Plan and Budget Request**

MPSC Members FY 2016

- Adventist Health Care, including:
 - Adventist Behavioral Health
 - Shady Grove Medical Center
 - Washington Adventist Hospital
- Adventist Rehabilitation Hospital
- Anne Arundel Medical Center
- Atlantic General Hospital
- Bon Secours Baltimore Health System
- Calvert Memorial Hospital
- Carroll Hospital Center
- Doctors Community Hospital
- Fort Washington Medical Center
- Frederick Regional Health System
- Garrett County Memorial Hospital
- Greater Baltimore Medical Center
- Holy Cross Hospital
- Johns Hopkins Howard County General Hospital
- Johns Hopkins Suburban Hospital
- Kennedy Krieger Institute
- Laurel Regional Hospital (Dimensions Health)
- Levindale Hebrew Geriatric Center & Hospital
- McCready Health
- MedStar Franklin Square Medical Center
- MedStar Good Samaritan Hospital
- MedStar Southern Maryland Hospital Center
- MedStar St. Mary's Hospital
- MedStar Union Memorial Hospital
- Mercy Medical Center
- Northwest Hospital
- Prince George's Hospital Center (Dimensions Health)
- Sheppard Pratt Health System
- Sinai Hospital of Baltimore
- Union Hospital of Cecil County
- UMD Baltimore Washington Medical Center
- UMD Charles Regional Medical Center
- UMD Medical Center
- UMD Medical Center Midtown Campus
- UMD Rehabilitation & Orthopaedic Institute
- UMD Shore Medical Center Dorchester
- UMD Shore Medical Center Easton
- UMD Shore Medical Center Chestertown
- UMD St. Joseph Medical Center
- UMD Upper Chesapeake Health
- Western Maryland Health System



Appendix I: MPSC Report to HSCRC on FY 2015 Results and
FY 2016 Program Plan and Budget Request

Mid Atlantic PSO Members FY 2016

- Anne Arundel Medical Center
- Atlantic General Hospital
- Bon Secours Hospital
- Calvert Memorial Hospital
- Carroll Hospital Center
- Doctors Community Hospital
- Frostburg Nursing and Rehabilitation Center
- Ft. Washington Medical Center
- Garrett County Memorial Hospital
- Greater Baltimore Medical Center
- Kennedy Krieger Institute
- Levindale Hebrew Geriatric Center
- MedStar St. Mary's Hospital
- MedStar Union Memorial Hospital
- Mercy Medical Center
- Meritus Medical Center
- Mt. Washington Pediatric Hospital
- Northwest Hospital
- SagePoint Senior Living Services
- Sheppard Pratt Health System
- Sinai Hospital
- UMD Harford Memorial Hospital
- UMD Shore Health at Chestertown
- UMD Upper Chesapeake Medical Center
- UMD Rehabilitation and Orthopaedic Institute
- Washington Adventist Hospital
- Western Maryland Health System



Strategic Direction

- Improve culture of patient safety
- Expand provider involvement
- Supporting provider efforts with regard to Waiver requirements and initiatives
- Continued coordination with statewide healthcare priorities:
 - HSCRC
 - OHQC
 - MHCC
 - DHMH



**Appendix I: MPSC Report to HSCRC on FY 2015 Results and
FY 2016 Program Plan and Budget Request**

FY 2017 Budget

REVENUE	FY 2016			FY 2017		
	MP SC	Consultants	Total	MP SC	Consultants	Total
Cash Contributions from MGA/DeMarva			100,000			100,000
Cash Contributions from Hospitals			75,000			30,000
Cash Contributions for Long-term Care			25,000			25,000
HSCRC Funding			972,000			874,800
Membership Dues			275,000			350,000
Education Session Revenue			22,000			14,000
Conference Registrations-Annual MedSafe Conference			3,000			2,000
Conference Registrations-Annual Patient Safety Conference			130,000			75,000
Sponsorships			130,000			140,000
Program Sales			60,000			60,000
Patient Safety Certification Revenue			-			85,000
DHDM Grant			200,000			200,000
Other Grants/Contributions			100,000			50,000
Total Revenue			2,092,000			2,005,800
EXPENSES	FY 2016	FY 2016	FY 2016	FY 2017	FY 2017	FY 2017
	MP SC	Consultants	Total	MP SC	Consultants	Total
Administration	551,250		551,250	551,750		551,750
Outpatient Dialysis (previously committed)	-		-	-		-
Programs			-			-
Education Sessions		78,000	78,000		69,000	69,000
Annual Patient Safety Conference		360,000	360,000		370,500	370,500
MEDSAFE Conference		55,000	55,000		33,250	33,250
Caring for IC	57,000	60,000	117,000	93,400	50,000	143,400
Patient/Family-Centered Care	-	-	-	-	-	-
Safety Initiatives-Perinatal/Neonatal	221,300	-	221,300	206,850	-	206,850
Safety Initiatives-Hand Hygiene	52,050	15,000	67,050	-	-	-
Safety Initiatives-Safe from Falls	24,600	500	25,100	-	-	-
Safety Initiatives-Adverse Event Reporting	15,600	85,000	100,600	25,100	40,000	65,100
Patient Safety Certification	117,400	52,000	169,400	132,300	15,000	147,300
Sepsis	71,500	87,900	159,400	38,200	47,150	85,350
Clean Environment	81,600	105,000	186,600	61,300	97,900	159,200
Patient Family Bundle				22,700	-	22,700
Med Rec				19,500	-	19,500
Surgical				19,500	-	19,500
Diagnosis Errors				19,500	-	19,500
Total Expenses	1,182,300	888,400	2,070,700	1,220,100	722,800	1,942,900
Net Income (Loss)			1,300			\$2,900



State of Maryland
Department of Health and Mental Hygiene

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Health Services Cost Review Commission

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Donna Kinzer
Executive Director

Stephen Ports
Principal Deputy Director
Policy and Operations

Vacant
Director
Payment Reform
and Innovation

Gerard J. Schmith
Deputy Director
Hospital Rate Setting

Sule Gerovlch, Ph.D.
Deputy Director
Research and Methodology

March 31, 2016

Ms. Erin Estey Hertzog, J.D., M.P.H.
Director, Health Law & Policy
Biotechnology Innovation Organization
1201 Maryland Avenue SW, Suite 900
Washington, DC 20024

Dear Ms. Hertzog:

I am writing in response to your letter of February 19, 2016 commenting on proposed amendments to Regulation .07-1 under COMAR 10.37.10 Rate Applications and Approval Procedures. You have expressed a concern that Maryland statute and regulation would expand eligibility for the 340B program without meeting federal standards as they apply to the Medicare Program's provider-based status and the Health Resources and Services Administration's 340B Outpatient Drug Discount Program. Please note that the proposed amendments on which you are commenting do not extend eligibility for the 340B program. That was done already under 2015 legislation and regulation. These amendments relate only to rate setting in anticipation of, and contingent upon, a hospital's attaining federal provider-based status and 340B approval.

You correctly state that the intent of the 2015 legislation was to allow Maryland hospitals to create provider-based departments as is already permitted in other states. The 2015 legislation requires that for an outpatient service of a hospital located at another hospital in a merged asset system to be regulated, the outpatient service must comply with "all federal requirements for the 340B program and applicable provisions of 42 CFR § 413.65." Those provisions include an attestation and determination of provider-based status by CMS. Therefore, if both provider-based status and 340B status have not been granted, the HSCRC will not approve rates for the service. The HSCRC intends to notify all Maryland hospitals by memorandum reiterating to them these requirements.

As to the question of rate setting for these aforementioned off-campus services under the new All-Payer Model waiver and the new requirements established under the Medicaid Program's

Covered Outpatient Drugs Final Rule, Maryland hospitals are already under a global budget system. Accordingly, the rates will be set utilizing the HSCRC's standard methodology, and the revenue will be included under the global budget revenue of the hospital that was granted provider-based status. However, 340B eligible hospitals that are willing to provide greater access to needed services by extending existing services in additional locations in the community under this legislation, will be allowed to retain the savings generated by the 340B discount for these extended services in their current global budget rather than having their global budgets reduced. Savings to the health care system will accrue through future growth of these services. In addition, because of the new All-Payer Model waiver, the Maryland Medicaid Program pays claims for drugs from 340B hospital providers at HSCRC rates.

Thank you for your comments, and I hope that I have satisfactorily addressed your concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "D. N. Phelps", written over a horizontal line.

Dennis N. Phelps
Associate Director,
Audit & Compliance



February 19, 2016

Diana Kemp
Regulations Coordinator
Health Services Cost Review Commission
4160 Patterson Avenue
Baltimore, MD 21215

Re: Notice of Proposed Action [16-043-P]

Dear Ms. Kemp:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to submit comments to the Health Services Cost Review Commission (HSCRC) in response to its proposal to amend Regulation .07-1 under COMAR 10.37.10 Rate Application and Approval Procedures (the "Proposed Rule").

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO represents an industry devoted to discovering new treatments and ensuring patient access to them. Accordingly, we support the 340B program as a mechanism to improve access to therapies for needy patients. We believe that compliance with all 340B program requirements—including those that relate to eligibility—is an important part of ensuring the sustainability of this program.

Last year, Maryland enacted legislation that purports to expand 340B eligibility with respect to certain outpatient facilities in the state. We write to reinforce the need to ensure that these facilities meet all applicable federal requirements with respect to 340B eligibility before they are able to obtain discounts through the program. In addition, we wish to ensure that Maryland is neither establishing an incentive nor creating a disincentive affecting eligible entities' participation in the federal 340B program through rates set by the HSCRC. We also urge HSCRC to articulate how rates set under the Proposed Rule will be implemented in the context of certain other federal requirements, namely the state's "All-Payer Model to Deliver Better Care at Lower Costs,"¹ and new requirements established under the Medicaid Program's Covered Outpatient Drugs Final Rule.²

I. HSCRC Should Ensure That Maryland Hospitals Are Aware of and Conforming to Federal Criteria for Child Site Participation in 340B.

On May 12, Governor Hogan signed into law HB 613, the stated purpose of which was to alter the definition of "hospital services" under the state's rate-setting statute "to

¹ <https://innovation.cms.gov/initiatives/Maryland-All-Payer-Model/>.

² 81 Fed. Reg. 5170 (Feb. 1, 2016).



include a hospital outpatient service that meets certain criteria for the purpose of making it possible for the hospital outpatient service to participate in a certain federal program”—specifically, 340B—“under rates set by the [HSCRC].”³ In other words, this measure purported to allow an outpatient facility to obtain 340B discounts even if it is part of a non-340B participating hospital so long as the outpatient facility is in the same “merged asset hospital system” as a 340B-participating hospital.

We believe that this new legislation, and its implementing regulations, have the potential to create confusion among Maryland hospitals. Specifically, we are concerned that Maryland hospital systems could begin treating an outpatient facility of one, non-340B-participating hospital in their “merged asset hospital system” as a child site of another, 340B-participating hospital in that system, due merely to the enactment of this new Maryland law. This would be an inappropriate interpretation of both state and federal law.

Rather, as we understood at the time of passage last year, the intent of HB 613 was merely to allow Maryland hospitals to create provider-based departments as is already permitted for hospitals in other states. Specifically, the Bill’s Fiscal and Policy Note states that: “In other states, hospitals are allowed to move their hospital outpatient departments to other sites and still maintain their drug discount, but because of Maryland’s unique hospital payment system, legislation is needed to allow this practice in the State.”⁴

Specifically, the Medicare program’s “provider-based” regulations state that, “[i]f a State health facilities’ cost review commission . . . finds that a particular facility or organization is not part of a provider, [the Centers for Medicare & Medicaid Services (CMS)] will determine that the facility or organization does not have provider-based status,” and thus cannot be included on the hospital’s Medicare cost report.⁵ Furthermore, given the reliance by the Health Resources and Services Administration (HRSA)⁶ on the Medicare cost report to determine 340B eligibility for hospital outpatient facilities (described in greater detail below), by extension, these facilities similarly cannot participate in 340B. Maryland is the only state in the country that has a rate-setting commission for purposes of the Medicare program, and is thus the only state to which this provision applies. This rate-setting commission, the HSCRC, has historically taken a limited view of the facilities that may permissibly be considered part of a hospital for Medicare cost reporting purposes. HB 613 was enacted to address this. However, this state legislation cannot expand child site eligibility beyond what is permitted under federal law.⁷

³ HB 613 <http://mgaleg.maryland.gov/2015RS/bills/hb/hb0613e.pdf> (effective October 1, 2015).

⁴ Maryland Department of Legislative Services, Maryland General Assembly 2015 Session, SB 5132, Fiscal and Policy Note – Revised, http://mgaleg.maryland.gov/2015RS/fnotes/bil_0003/sb0513.pdf.

⁵ See 42 C.F.R. § 413.65(d)(1) (emphasis added).

⁶ HRSA is the federal agency charged with administering the 340B program.

⁷ This is recognized by the underlying state statute, which provides that, in order to participate in 340B, a facility must “comply with all federal requirements for the 340B program and applicable provisions of [the Medicare provider-based regulations].” Md. HEALTH-GENERAL Code Ann. § 19-201(d)(2)(iii) (citing 42 C.F.R. 414.65).



Nothing in the 340B statute provides for any offsite hospital outpatient facility to participate in the 340B program; rather 340B eligibility for hospital “child sites” is a doctrine developed by HRSA. This doctrine cannot legitimately be used to extend 340B eligibility to offsite facilities—even facilities within a “merged asset hospital system”—that are distinct from the covered entity hospital and serve distinct patient populations that the 340B Program was not created to assist. Indeed, to ensure that an outpatient facility of a 340B-participating hospital “is considered an integral part of the ‘hospital’ and therefore eligible for section 340B drug discounts,” HRSA has long required the facility to be “a reimbursable facility included on the hospital’s Medicare cost report.”⁸ Conditions for an outpatient facility’s inclusion on a hospital’s Medicare cost report are defined, in turn, under federal “provider-based status” regulations promulgated by CMS for purposes of the Medicare program (described above). Under these regulations, in order for the facility to appear on the hospital’s cost report, the outpatient facility and the hospital generally must be operated under the same state license, and be both clinically and financially integrated.⁹ A more casual affiliation will not suffice.

We therefore urge HSCRC to provide clear guidance to the state’s hospitals that an outpatient facility must meet all of the applicable Medicare requirements for inclusion on the 340B-participating hospital’s cost report, and appear on that cost report, before it may be enrolled as a child site of that hospital for purposes of the 340B program. HSCRC should further clarify that merely being part of the same “merged asset hospital system” would not necessarily allow an outpatient facility to meet these requirements, which require a large degree of clinical and financial integration, as well as common state licensure, as prescribed in Medicare regulations. Finally, we urge HSCRC to collaborate with HRSA to ensure that the state’s hospitals are, in practice, operating in conformity with these requirements.

II. Covered Entity Participation in the 340B Program Is Voluntary; HSCRC Should Not Effectively Compel 340B Participation Using its Rate-Setting Authority.

The 340B Program plays an important role in America’s healthcare system by supporting needy patient access to outpatient drugs. However, as HRSA itself has said, with this important benefit comes “significant responsibility.”¹⁰ Covered entities participating in the 340B program have considerable registration, certification, and recordkeeping requirements to enable compliance with numerous federal program integrity requirements (e.g., prohibitions on duplicate discounts and diversion), and are subject to selective federal audits.¹¹ Those covered entities found out of compliance with these program requirements may be liable for refunds of discounts received from manufacturers

⁸ 59 Fed. Reg. 47,884 (Sept. 19, 1994). See also 80 Fed. Reg. 52,300 (Aug. 28, 2015). In contrast, HRSA has made clear that “free-standing clinics of the hospital that submit their own cost reports using different Medicare provider numbers (not under the single hospital Medicare provider number) would not be eligible for this benefit.” 59 Fed. Reg. at 47,885.

⁹ 42 C.F.R. § 414.65.

¹⁰ HRSA, Program Requirements, <http://www.hrsa.gov/opa/programrequirements/> (last accessed Feb. 1, 2016).

¹¹ HRSA, Program Integrity, <http://www.hrsa.gov/opa/programintegrity/index.html> (last accessed Feb. 1, 2016).



and/or removal from the program. As these risks and responsibilities are associated with real costs for covered entities, and this cost-benefit analysis will vary entity-by-entity, we believe that each entity should be able to independently evaluate whether such costs are outweighed by the potential benefits of program participation on a case-by-case basis.

Furthermore, mounting evidence suggests that the 340B program has been a key driver behind provider consolidation and shifts in the site of care nationwide, and that these trends have had negative implications for patients and others.¹² Indeed, the availability of deeply discounted 340B pricing allows 340B hospitals to generate higher net revenues than independent physician offices for administering the same medicine, which creates financial incentives for 340B hospitals to purchase independent physician practices and bring them under the 340B umbrella. This growth has created market distortions, negatively affecting community physician clinics, and lead to unintended consequences in billing patterns, increasing the cost of care for patients.¹³ We believe that the state should be careful not to exacerbate these trends.

We are therefore concerned that the Proposed Rule does not specify that the 340B-specific rates would apply only to those entities that are actually enrolled in the 340B program, including any compliant child sites. Instead, the Proposed Rule suggests that the rates could apply to all sites with provider-based status.

This is troubling because provider-based status is a Medicare-specific designation that a hospital may obtain for a given outpatient facility without ever intending to enroll that facility as a child site in the 340B program—not to mention that 340B child site eligibility necessarily requires that the parent hospital be eligible for, and enrolled in, the 340B program, a category that represents only a subset of Maryland hospitals. However, if HSCRC were to apply to all provider-based facilities a 340B-specific reimbursement rate—which presumably would be lower than the otherwise-applicable rates—it could put those provider-based facilities that do not actually participate in the 340B program at a considerable disadvantage. Specifically, these facilities would be subject to the lower 340B rate, even though they would not have made (deeply discounted) purchases through the

¹² For example, the most recent oncology practice impact funded by the Community Oncology Alliance found that 340B hospitals accounted for three-quarters of community oncology clinics bought over a two-year period. See Aaron Vandervelde, *340B Growth and the Impact on the Oncology Marketplace* (Sept. 2015). New data from Avalere Health finds that 340B hospitals are more likely than other hospitals to purchase independent physician offices that administer medicines. Avalere Health. *Hospital acquisitions of physician practices and the 340B program* (June 8, 2015). The study authors found that 61 percent of hospitals identified in the study as potentially acquiring physician practices participated in the 340B Program, as compared to a 45 percent 340B participation rate among all hospitals in the data set. Also, a 2014 *Health Affairs* study concluded that 340B is a “powerful contributor” to driving these hospital acquisitions of physician practices. Bradford Hirsch, Suresh Balu & Kevin Shulman, *The Impact of Specialty Pharmaceuticals as Drivers of Health Care Costs*. 33 *Health Affairs* 1714-20 (Oct. 2014).

¹³ BRG Healthcare, *Growth of the 340B Program: Past Trends, Future Projections* (Nov. 2014); BRG Healthcare, *340B Growth and the Impact on the Oncology Marketplace* (Sept. 2015), Available at http://www.communityoncology.org/pdfs/BRG_COA_340B-Report_9-15.pdf; U.S. Gov’t Accountability Office (GAO), *Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals* (June 2015).



340B program. As a consequence, while these facilities might have very legitimate reasons for not participating in the 340B program, subjecting them to a lower, 340B-specific reimbursement rate could effectively compel them to nonetheless participate (or face significant challenges providing patient access to medications). To avoid this result, we urge HSCRC to clarify that the new rates would apply only to those facilities that are actually participating in 340B and thus have access to discounts through the program. Furthermore, while the Proposed Rule suggests that the rates may go into effect “in anticipation” of a facility obtaining 340B status, we urge the HSCRC to also clarify that the new rates would apply only once the facility has enrolled in the 340B Program as an eligible child site—a process that can take up to 18 months after the facility meets the applicable eligibility criteria.¹⁴ Finally, to further avoid applying 340B-specific rates to non-340B utilization, HSCRC also should specify that—with respect to Medicaid utilization—the new rates will apply only to those facilities that “carve in” their Medicaid patients (i.e., dispense 340B drugs to their Medicaid patients).¹⁵

III. HSCRC Should Clarify How Rates Set Under the Proposed Rule will Interact with the State’s “All-Payer Model to Deliver Better Care and Lower Costs,” as well as the New Requirements Established by the Covered Outpatient Drugs Final Rule.

We further note that the Proposed Rule does not describe how the HSCRC’s new rate-setting authority will be exercised in the context of two other federal requirements. First, as you are aware, Maryland has entered into a five-year demonstration with the Centers for Medicare & Medicaid Innovation (CMMI) to utilize the state’s unique all-payer rate-setting structure to set new cost and cost-savings benchmarks for Maryland hospitals based on total hospital revenues within an all-payer cap. The cost-related requirements of this demonstration include that Maryland will:

- Transition virtually all hospital revenue to a global payment model within 5 years;
- Limit all-payer per capita hospital growth (both inpatient and outpatient) to 3.58 percent for 2014 through 2016 (a benchmark derived from the state’s compounded annual growth rate in per capita gross state product [GSP]) with the potential for change in the growth rate ceiling in 2017 and 2018 based on changes in the GSP;

¹⁴ Indeed, even those facilities eligible for provider-based status may not be immediately eligible to participate in 340B. Instead, the facilities must first appear as a reimbursable line on the parent hospital’s Medicare cost report, and it is our understanding that it can take up to 18 months for a facility to appear on the cost report of its parent hospital.

¹⁵ Both the 340B and Medicaid statutes prohibit “duplicate discounts” (i.e., obtaining both a 340B discount and Medicaid drug rebate on the same unit of drug). To implement this prohibition, HRSA requires covered entities to either “carve-in” or “carve-out.” Those entities that “carve-in” have elected to dispense 340B products to their Medicaid patients and thus must report their provider ID to HRSA to be included on the “Medicaid Exclusion File,” which states then use to exclude such utilization from their Medicaid Drug Rebate invoices. On the other hand, those covered entities that “carve out,” have elected to dispense non-340B (i.e., commercially purchased) drugs to their Medicaid patients. While these entities are enrolled and participate in the 340B program, the drugs they dispense to their Medicaid patients are not purchased under the 340B Program and thus should not be reimbursed under the 340B-specific reimbursement rates.



- Limit the state's annual Medicare per capita hospital cost growth to a rate lower than the national annual per capita growth rate per year for 2015-2018; and
- Show at least \$330 million in savings over the five-year demonstration (calculated as the difference between Maryland's Medicare per capita total hospital cost growth and that of Medicare nationally).

We urge the HSCRC to clarify how rates set under the Proposed Rule will be implemented in the context of this demonstration, particularly the requirement that the state transition to a global payment for virtually all hospital revenues over the next few years.

Second, it is similarly unclear whether the rates set under the Proposed Rule are meant to implement the new requirement—added by the Medicaid Program's Covered Outpatient Drug Final Rule—that state Medicaid programs set 340B-specific reimbursement rates. We urge the HSCRC to clarify whether this is the intent of the Proposed Rule and, if so, to identify the process by which the state will seek CMS approval for a state plan amendment (SPA) to implement these provisions in accordance with applicable federal requirements.¹⁶

IV. Conclusion

We thank you for this opportunity to comment on the Proposed Rule. Please do not hesitate to contact me if BIO can be of any assistance as HSCRC continues its efforts to implement HB 613 in conformity with both state and federal law. We thank you for your attention to these important matters.

Respectfully Submitted,

/s/

Erin Estey Hertzog, J.D., M.P.H.
Director, Health Law & Policy

¹⁶ These federal requirements are detailed both in the preamble to the Medicaid Program's Covered Outpatient Drugs Final Rule, 81 Fed. Reg. at 5317-18, as well as in a letter to State Medicaid Directors subsequently issued by CMS. See CMS, Letter to State Medicaid Directors, Re: Implementation of the Covered Outpatient Drug Final Regulation Provisions Regarding Reimbursement for Covered Outpatient Drugs in the Medicaid Program (Feb. 11, 2016), available at: <https://www.medicare.gov/federal-policy-guidance/downloads/smd16001.pdf>.

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Health Services Cost Review Commission

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March 24, 2016

Mr. John A. Murphy III
PhRMA
950 F Street, NW, Suite 300
Washington, DC 20004

Dear Mr. Murphy:

I am writing in response to your letter of February 22, 2016 commenting on proposed amendments to Regulation .07-1 under COMAR 10.37.10 Rate Applications and Approval Procedures. You have expressed a concern that Maryland statute and regulation would expand eligibility for the 340B program without meeting federal standards as they apply to the Medicare Program's provider-based status and the Health Resources and Services Administration's 340B Outpatient Drug Discount Program. Please note that the proposed amendments on which you are commenting do not extend eligibility for the 340B program. That was done already under 2015 legislation and regulation. These amendments relate only to rate setting in anticipation of, and contingent upon, a hospital's attaining federal provider-based status and 340B approval.

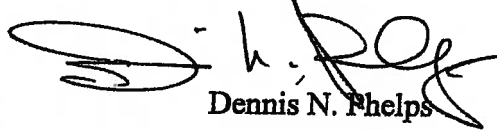
Let me first explain briefly why the legislation was necessary. Prior to the 2015 legislation, Maryland law creating the Health Services Cost Review Commission's (HSCRC's) authority to regulate hospital rates limited the HSCRC's jurisdiction to outpatient services provided at the hospital with one exception, Freestanding Medical Facilities. As you noted in your letter, the Medicare program's regulations require that as a State with an agency or commission that regulates hospital rates, Maryland's HSCRC must find that that an off-campus facility is part of a hospital in order to be granted provider-based status. However, because the HSCRC's jurisdiction was limited to outpatient services provided "at-the-facility," Maryland hospitals were not able to be granted off-site provider-based status as could hospitals in the rest of the nation. Maryland 2015 legislation makes it possible for the extension of existing outpatient services associated with the 340B program to additional community locations.

The 2015 legislation states that for an outpatient service of a hospital located at another hospital in a merged asset system to be regulated, the outpatient service must comply with "all federal requirements for the 340B program and applicable provisions of 42 CFR § 413.65." Those provisions include an attestation and determination of provider-based status by CMS. Therefore, if both provider-based status and 340B status have not been granted, the HSCRC will not approve rates for the service. The HSCRC intends to notify all Maryland hospitals by memorandum informing them of these requirements.

As to the question of rate setting for these aforementioned off-campus services under the new All-Payer Model waiver, Maryland hospitals are already under a global budget system. Accordingly, the rates will be set utilizing the HSCRC's standard methodology, and the revenue will be included under the global budget revenue of the hospital that was granted provider-based status.

Thank you for your comments, and I hope that I have satisfactorily addressed your concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis N. Phelps", written over a horizontal line.

Dennis N. Phelps
Associate Director,
Audit & Compliance



February 22, 2016

Diana Kemp
Regulations Coordinator
Health Services Cost Review Commission
4160 Patterson Avenue
Baltimore, MD 21215

Re: Notice of Proposed Action [16-043-P]

Dear Ms. Kemp:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments to the Health Services Cost Review Commission (HSCRC) regarding proposed amendments to Regulation .07-1 under COMAR 10.37.10 Rate Application and Approval Procedures.

PhRMA is a voluntary non-profit organization representing the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to lead longer, healthier, and more productive lives. PhRMA and its members support the federal 340B program, which was established to help make prescription drugs more accessible to uninsured or vulnerable patients, and we appreciate the ability to comment on these proposed rules.

In light of last year's legislative changes to Maryland law that seemed designed to expand eligibility for the 340B program in Maryland, we want to emphasize at the outset our hope that the HSCRC is working with each potentially eligible entity to ensure that it meets the *federal* standards for participation in the 340B program. Further, we urge HSCRC to examine the goals of this proposed rule to ensure that it would set rates that are consistent with other federal requirements.

Federal Rules Outline Entity Qualification for 340B Participation

Initially, we are concerned that with the passage of this new legislation last year, Maryland hospitals may be confused about their obligations under both state and federal law related to 340B eligibility. Specifically, we are concerned that, due to enactment of this legislation, Maryland hospital systems could begin treating an outpatient facility of a non-340B hospital in their "merged asset hospital system" as a child site of a 340B hospital in that system. We do not believe this practice would conform to federal rules.

Specifically, the Medicare program's "provider-based" regulations state that, "[i]f a State health facilities' cost review commission . . . finds that a particular facility or organization is not part of a provider, CMS will determine that the facility or organization does not have provider-based status" (42 CFR § 413.65z (d) (1) (emphasis added), which should prevent the facility from being included as reimbursable on the hospital's Medicare cost report. Under 340B program guidance issued by the Health Resources and Services Administration (HRSA)¹ an outpatient facility of a 340B hospital can only

¹ HRSA is the federal agency charged with administering the 340B program.

participate in the 340B program if it is included as reimbursable on the hospital's Medicare cost report.² Maryland is the only state in the country that has a rate-setting commission for purposes of the Medicare program, and is thus the only state to which 42 CFR § 413.65(d)(1) -- which essentially permits a rate -setting commission to veto provider-based status for a facility -- applies. HSCRC has historically taken a limited view of the facilities that may permissibly be considered part of a hospital for Medicare cost reporting purposes. HB 613 was enacted to address this. However, this state legislation cannot expand child site eligibility beyond what is permitted under federal law.

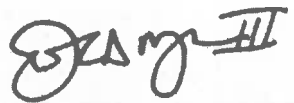
To be sure, nothing in the 340B statute provides for any offsite hospital outpatient facility to participate in the 340B program; instead, HRSA has developed a policy for qualification of "child sites" under 340B. This policy, however, cannot legitimately be used to extend 340B eligibility to offsite facilities—even facilities within a "merged asset hospital system"—that are distinct from the covered entity hospital. Indeed, HRSA has long required hospital outpatient facilities that participate in 340B to be reimbursable facilities included on the hospital's Medicare cost report because it believes this shows that the facility is "an integral part of the 'hospital' and therefore eligible for section 340B discounts."³ Accordingly, HSCRC should make clear to Maryland hospitals that federal law governs 340B eligibility and simply existing within a merged-asset hospital system in Maryland is not sufficient to meet the federal child site requirements.

Interaction of the Proposed Rule and Maryland Demonstration Programs

As you are no doubt aware, Maryland is currently engaged in a demonstration with CMS' Centers for Medicare & Medicaid Innovation (CMMI) to utilize the State's unique all-payer rate-setting structure to set new cost and cost-savings benchmarks for Maryland hospitals based on total hospital revenues within an all-payer cap. Among other things, the demo requires the state to move to a global payment model for most hospitals within 5 years, to limit per capita hospital growth significantly, and to show at least \$330 million in savings over the course of the demonstration. We urge the HSCRC to articulate how the rates to be set under this proposed rule will be implemented in the context of this demonstration and (in particular) how this rate setting will reconcile with a future global payment system at the end of the demonstration.

Again, PhRMA appreciates the opportunity to submit comments to the proposed rule amendments and please contact us with any questions.

Sincerely,



John A. Murphy III

JMurphy@PHRMA.org | 202-835-3569

² 59 Fed. Reg. 47884 (Sept. 19, 1994).

Legislative Update

The Legislative Update will be presented at the Commission Meeting

State of Maryland
Department of Health and Mental Hygiene



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Health Services Cost Review Commission

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TO: Commissioners
FROM: HSCRC Staff
DATE: April 13, 2016
RE: Hearing and Meeting Schedule

May 11, 2016 To be determined - 4160 Patterson Avenue
HSCRC/MHCC Conference Room

June 8, 2016 To be determined - 4160 Patterson Avenue
HSCRC/MHCC Conference Room

Please note that Commissioner's binders will be available in the Commission's office at 11:45 a.m.

The Agenda for the Executive and Public Sessions will be available for your review on the Thursday before the Commission meeting on the Commission's website at <http://www.hsrc.maryland.gov/commission-meetings-2016.cfm>

Post-meeting documents will be available on the Commission's website following the Commission meeting.