

2018 Pre-Filed Testimony Hospitals and Provider Organizations



**As part of the
*Annual Health Care
Cost Trends Hearing***

Notice of Public Hearing

Pursuant to M.G.L. c. 6D, § 8, the Massachusetts Health Policy Commission (HPC), in collaboration with the Office of the Attorney General and the Center for Health Information and Analysis, will hold a public hearing on health care cost trends. The hearing will examine health care provider, provider organization, and private and public health care payer costs, prices, and cost trends, with particular attention to factors that contribute to cost growth within the Commonwealth's health care system.

Scheduled hearing dates and location:

Tuesday, October 16, 2018, 9:00 AM
Wednesday, October 17, 2018, 9:00 AM
Suffolk University Law School
First Floor Function Room
120 Tremont Street, Boston, MA 02108

The HPC will call for oral testimony from witnesses, including health care executives, industry leaders, and government officials. Time-permitting, the HPC will accept oral testimony from members of the public beginning at approximately 3:30 PM on Tuesday, October 16. Any person who wishes to testify may sign up on a first-come, first-served basis when the hearing commences on October 16.

Members of the public may also submit written testimony. Written comments will be accepted until October 19, 2018, and should be submitted electronically to HPC-Testimony@mass.gov, or, if comments cannot be submitted electronically, sent by mail, post-marked no later than October 19, 2018, to the Massachusetts Health Policy Commission, 50 Milk Street, 8th Floor, Boston, MA 02109, attention Lois H. Johnson, General Counsel.

Please note that all written and oral testimony provided by witnesses or the public may be posted on the HPC's website: www.mass.gov/hpc.

The HPC encourages all interested parties to attend the hearing. For driving and public transportation directions, please visit: <http://www.suffolk.edu/law/explore/6629.php>. Suffolk University Law School is located diagonally across from the Park Street MBTA station (Red and Green lines). Parking is not available at Suffolk, but information about nearby garages is listed at the link provided. The event will also be livestreamed on the [HPC's homepage](#) and available on the [HPC's YouTube Channel](#) following the hearing.

If you require disability-related accommodations for this hearing, please contact HPC staff at (617) 979-1400 or by email at HPC-Info@mass.gov a minimum of two (2) weeks prior to the hearing so that we can accommodate your request.

For more information, including details about the agenda, expert and market participant witnesses, testimony, and presentations, please check the [Annual Cost Trends Hearing section](#) of the HPC's website. Materials will be posted regularly as the hearing dates approach.

Instructions for Written Testimony

If you are receiving this, you are hereby required under M.G.L. c. 6D, § 8 to submit written pre-filed testimony for the 2018 Annual Cost Trends Hearing. On or before the close of business on **September 14, 2018**, please electronically submit written testimony to: HPC-Testimony@mass.gov. Please complete relevant responses in the provided template. If necessary, you may include additional supporting testimony or documentation in an Appendix. Please submit any data tables included in your response in Microsoft Excel or Access format.

We encourage you to refer to and build upon your organization's 2013, 2014, 2015, 2016, and/or 2017 pre-filed testimony responses, if applicable. Additionally, if there is a point that is relevant to more than one question, please state it only once and make an internal reference. **If a question is not applicable to your organization, please indicate so in your response.**

The testimony must contain a statement from a signatory that is legally authorized and empowered to represent the named organization for the purposes of this testimony. The statement must note that the testimony is signed under the pains and penalties of perjury. An electronic signature will be sufficient for this submission.

If you have any difficulty with the templates, did not receive the email, or have any other questions regarding the pre-filed testimony process or the questions, please contact HPC staff at HPC-Testimony@mass.gov or (617) 979-1400.

HPC Contact Information

For any inquiries regarding HPC questions, please contact HPC-Testimony@mass.gov or (617) 979-1400.

AGO Contact Information

For any inquiries regarding AGO questions, please contact Assistant Attorney General Sandra Wolitzky at Sandra.Wolitzky@mass.gov or (617) 963-2030.

HPC Pre-Filed Testimony Questions

1) STRATEGIES TO ADDRESS HEALTH CARE SPENDING GROWTH

To address excessive health care costs that crowd out spending on other needs of government, households, and businesses alike, the Massachusetts Health Policy Commission (HPC) annually sets a statewide target for sustainable growth of total health care spending. From 2013 to 2017, the benchmark rate was set at 3.6% growth. For the first time for 2018 and again for 2019, the HPC exercised its authority to lower this target to a more ambitious growth rate of 3.1%, the lowest level allowed by state law. Achieving this reduced growth rate in the future will require renewed efforts by all actors in the health care system, supported by necessary policy reforms, to achieve savings without compromising quality or access.

- a) What are your organization's top areas of concern for the state's ability to meet the 3.1% benchmark? Please limit your answer to no more than three areas of concern.

1. Cambridge Health Alliance's (CHA) top concern is to promote access to affordable health care through policy action to address the longstanding acute hospital rate inequity that permeates the payment systems, including alternative payment methods (APMs) and accountable care organizations (ACOs) designed to promote population health. The persistent gap in adequate commercial health plan rates for community and safety net hospitals imperils the high value and affordable care they provide and community-appropriate care. If greater care is provided by high value, lower relative price community hospitals versus higher price hospitals, this keeps care affordable and accessible. The commercial insurance system has failed to address wide rate disparities. In the most recent available data, CHA has seen our relative price (0.754) ranking decline to the six lowest paid hospital in the state.

2. There are access barriers for important levels of care such as mental health and substance use disorders, which are exacerbated by inadequate reimbursement by all payers. Further, current risk adjustment methodologies do not adequately account for behavioral health complexity across all payers.

3. A looming threat to the ability to meet the statewide cost growth benchmark and to access to care overall is the pending mandated nurse staffing ratio ballot question. Independent cost estimates found that the staffing proposal will add \$1.3 billion in costs in the first year and over \$1 billion annually thereafter. For CHA, the annual costs of meeting the ratios would be in excess of \$13 million annually, assuming qualified staff are available at current rates. At a time when affordable health care is the focus, patients and businesses would face higher insurance premiums and out-of-pocket expenses.

In addition, there will be far-reaching implications for care access, which include not only hospital care (subject to the mandated staffing ratios) but also to ambulatory and community settings as nurses are recruited to fulfill hospital staffing ratios. Ultimately, this will adversely impact payment reforms intended to improve population health and costs.

Hospitals would be limited in the services they can provide at a given time due to rigid ratios, resulting in increased waiting times in emergency rooms or delays in life-saving care. Of particular note is the adverse impact on access to behavioral health care, which represents nearly one-half of the inpatient care at CHA. Mandated nurse staffing ratios, if imposed, will translate into a loss of access of more than 1000 behavioral health beds, according to a report of the Massachusetts Association of Behavioral Health Systems. Proposed nurse staffing ratios are

not consistent with behavioral health clinical standards of care and do not account for the multi-disciplinary clinical team approach.

- b) What are the top changes in policy, market behavior, payment, regulation, or statute your organization would recommend to address these concerns?

1. Near-term policy action to address unwarranted acute hospital payment rate variation is an urgent priority, particularly as it relates to low-relative price community and safety net hospitals that are not part of the large systems forming in Massachusetts. A structural solution is needed to improve unsustainably low commercial rates for community and safety net hospitals to a minimum of 90% of the statewide average relative price in order to support their essential capacity and local access, and avoid the increased costs if care that can be delivered in the community is concentrated at higher price medical centers.

In addition, APM methodologies must create greater incentives for more efficient ACOs through greater weighting of the average market rate in developing their global budgets. Adequate public payer APM rates are necessary to sustain promising reform. ACOs that demonstrate value should not be subject to unrealistic short term savings expectations versus payment more aligned with the average market rate. This has emerged as a challenge within the Medicaid ACOs (through the use of a network variation factor), which reduces global budgets for more efficient ACOs and maintains higher values for less efficient providers.

2. Investments in behavioral health rates are needed. Behavioral health complexity must be incorporated into payer risk adjustment models to adequately reflect care coordination and management requirements.

3. Supportive policies are recommended to foster a variety of quality innovations and cost-effective care. For example, actions to require data sharing across the care continuum (such as admission, discharge, and transfer reports) will help coordinate care and prevent avoidable care. Another area of policy guidance is unifying the variation and scope of quality measures across multiple payers. Payers should be guided to accept data from electronic health records (including data during the measurement period when the patient was part of another insurer's panel). These arbitrary rules have the potential to result in duplication of testing and costs. Quality performance thresholds must reflect reasonable levels that account for patient circumstances such as patient rights, cultural/religious beliefs, and social factors.

4. Additional incentives and monitoring are needed to promote community-hospital appropriate care, particularly in light of proposed large health systems developing. In addition, ACO service area limitations imposed by the MassHealth program have resulted in patient disruptions to care, particularly to primary care relationships, and challenges in connecting patients to culturally appropriate community-based care.

- c) What are your organization's top strategic priorities to reduce health care expenditures? Please limit your answer to no more than three strategic priorities.

CHA is currently advancing several strategies to deliver efficient care and coordinate cost effective total medical expenditures, particularly under APMs. Approximately, 48% of CHA's primary care patient population in APMs as of September 2018:

- *Medicare: Medicare Shared Savings, Medicare Advantage, Senior Care Options and Elder Service Plans;*

- *Medicaid: launched MassHealth ACO; and*
- *Commercial: Blue Cross Blue Shield, Harvard Pilgrim Health Care, and Tufts Health Plan.*

CHA is closely watching the state’s contemplated demonstration process for OneCare and Senior Care Options to further enhance APM expansion.

In these initiatives, CHA is focused on greater use of community-appropriate care in the least restrictive setting in the community. We are also working to address social determinants of health, faced by a large segment of our patient population, in collaboration with community and social service organizations.

We continue to mature our care management processes, including the opportunity with selected payers to receive delegated care management functions with a corresponding allocation of the administrative per member per month funds to support these efforts most proximate to patient care.

2) INFORMATION ABOUT ALTERNATIVE CARE SITES

The HPC recently released a [new policy brief](#) examining the significant growth in hospital and non-hospital based urgent care centers as well as retail clinic sites in Massachusetts from 2010 to 2018. Such alternative, convenient points of access to health care have the potential to reduce avoidable and costlier emergency department (ED) visits.

Question Instructions: *If your organization does not own or operate any alternative care sites such as urgent care centers, please only answer questions (e) and (f) below. For purposes of this question, an urgent care center serves all adult patients (i.e., not just patients with a pre-existing clinical relationship with the center or its providers) on a walk-in (non-appointment) basis and has hours of service beyond normal weekday business hours. Information requested in question (a) below may be provided in the form of a link to an online directory or as an appended directory.*

- a) Using the most recent information, please list the names and locations of any alternative care sites your organization owns or operates in Massachusetts. Indicate whether the site is corporately owned and operated, owned and operating through a joint venture, or a non-owned affiliate clinical affiliate.

NA

- b) Please provide the following aggregate information for calendar year 2017 about the alternative care sites your organization owns or operates in Massachusetts, including those operated through a joint venture with another organization (information from non-owned affiliates should not be included):

Number of unique patient visits	NA
Proportion of gross patient service revenue that was received from commercial payers, Medicare, MassHealth, Self-Pay, and Other	NA
Percentage of patient visits where the patient is referred to a more intensive setting of care	NA

- c) For the alternative care sites your organization owns or operates in Massachusetts, briefly describe the clinical staffing model, including the type of clinicians (e.g., physicians, nurse practitioners, physician assistants, paramedics, nurses). If different models are used, describe the predominant model.

NA

- d) For the alternative care sites your organization owns or operates in Massachusetts, briefly describe the method and timeliness of how the medical record of a patient's visit to an alternative care site is shared with that patient's primary care provider (e.g., interoperable electronic health record, secure email transfer, fax). What barriers has your organization faced in sharing real-time information about patient visits to your alternative care sites with primary care providers or other health care providers?

NA

- e) Besides establishing alternative care sites, what other strategies is your organization pursuing to expand timely access to care with the goal of reducing unnecessary hospital utilization (e.g., after-hours primary care, on-demand telemedicine/virtual visits).

CHA operates 13 primary care clinic locations, all of which offer evening hours and 6 of which offer evening hours three or four nights each week. In addition, 3 locations operate on Saturday and one on Sunday. All locations have schedules which will accommodate same day and walk in appointments. Each site offers physician and nursing consultative services by phone, during both regular and off hours.

CHA primary care also prioritizes post-inpatient discharge follow-up with our patients to prevent avoidable admissions and readmissions.

Enhanced risk stratification tools and techniques are used to identify patients that are at risk for or are predicted to have a potential for a future admission. CHA is initiating the incorporation of social determinants of health into risk stratification to help prioritize the need for community and other non-clinical interventions to help reduce avoidable acute care. Another area of focus is earlier identification of patients who may consider palliative care and hospice services based on provider assessment and risk stratification tools.

CHA is also advancing evidence-based pathways for high prevalence chronic health conditions that are sensitive to appropriate ambulatory care and can result in avoidable health care utilization due to gaps in treatment or follow-up. A specific focus is on chronic obstructive pulmonary disease, congestive heart failure, hypertension, and co-morbid depression. CHA is also advancing care management for behavioral health conditions, including substance use disorder and serious mental illness.

- f) Please comment on the growth of alternative care sites in Massachusetts, including implications for your organization as well as impacts on health care costs, quality, and access in Massachusetts.

The proliferation of urgent care centers or alternative care sites (such as radiology and outpatient surgical centers) proximate to hospital and health center sites (and the location of such centers to attract commercially insured patients in more affluent communities) could destabilize existing community-based providers who serve all patients and payers. In general,

many retail and urgent care providers focus on commercial and more affluent communities, which is evident in our primary service area with 8 in Cambridge and only 6 across the rest of the communities we serve.

Many of the chains and large networks of urgent care centers (some of which are affiliated with market-dominant health systems) make it clear to prospective patients to expect to pay for copays and uncovered costs, which can be unwelcoming to lower-income patients. One chain has a new credit card on file policy that asks patients to provide their credit card up front so that the chain can auto-collect costs not covered by the insurance company, which can establish a barrier for lower-income patients. In addition, the chains and large networks of urgent care centers are not generally equipped to handle complex patients and mental health and substance use needs. This will result in a higher burden of care for vulnerable populations at hospital and health center sites.

Care at urgent care centers can be episodic and transactional in nature versus integrated with the patient's primary care and overall care plan. This has resulted in the introduction of new care delivery sites that do not have the same accountability and have limited requirements relative to quality performance or gaps in care, network management, data sharing and reconnecting patients to primary care.

3) STRATEGIES TO SUPPORT PROVIDERS TO ADDRESS HEALTH-RELATED SOCIAL NEEDS

Earlier this year, the HPC held a special event entitled, [*Partnering to Address Social Determinants of Health: What Works?*](#), where many policymakers, experts, and market participants all highlighted the need for health care systems to partner with community-based organizations to address patients' and families' health-related social needs (e.g., housing stability, nutrition, transportation) in order to improve health outcomes and slow the growth in health care costs.

- a) What are the primary barriers your organization faces in creating partnerships with community-based organizations and public health agencies in the community/communities in which you provide care? [check all that apply]
 - Legal barriers related to data-sharing
 - Structural/technological barriers to data-sharing
 - Lack of resources or capacity of your organization or community organizations
 - Organizational/cultural barriers (***Not all social service organizations will accept referrals, including for housing. Many such organizations do not provide navigation assistance for individuals or information to collaborating providers on the status of the individual in accessing services.***)
 - Other: ***Reimbursement and payment policy disconnects with community-based organizations.***

- b) What policies and resources, including technical assistance or investments, would your organization recommend to the state to address these challenges?

CHA is committed and enthusiastic about addressing the health-related social needs of our patients. We are in the midst of undertaking a social determinants of health screening and referral initiative for our patients. Current referrals for food services in conjunction with Project Bread are working well at this time.

We commend MassHealth for including initiatives and support for social determinants of health in its recent MassHealth ACO and MCO programs. Other payers, including commercial payers, should be encouraged to adopt supportive payment policies for social factors related to health, as health care providers would like to care for their entire patient population in a consistent way.

Based on our initial work, we have identified several areas (bulleted below) where MassHealth and other state agencies could be of assistance with addressing opportunities for improving program implementation and eligibility for social services, investments, and technical assistance.

- *A role is recommended for the state in maintaining a directory of active social service agencies by geography for use by health care providers working to address social factors in health, due to the time intensity and frequent updates (that could be integrated in electronic medical records).*
- *This will help in identifying geographic areas where there are relatively few social service agencies and collaborating toward incentives or systems to support agencies in those areas. In some of our areas, there are relatively few social service agencies. In general, there are concerns about the capacity of various social services agencies to take on referrals, given current resource constraints.*
- *Optimally, there would be a new state opportunity for enhanced funding for community-based organizations both 1) to build additional capacity (staff and resources) to accommodate increased demand resulting from the implementation of the MassHealth ACO and other initiatives and 2) to build secure data systems to enable real-time, protected information sharing.*
- *A role is suggested for MassHealth to help in fostering relationships between health systems and social service agencies in the flexible funds program. Having each health system talk independently to each service agency will create duplicative work on both sides and could lead to/exacerbate inequities. In addition, there is an opportunity for the provision of technical assistance and trainings to providers/practices and community-based organization on best practices regarding establishing partnerships.*
- *Transportation has emerged as a leading concern based on initial pilots of screening. A number of patients are in need of transportation support, and there are opportunities to work with MassHealth to streamline and improve the current process in applying for MassHealth benefits (through the PT-1 form). The PT1 form is currently not a user friendly tool, and each application is for specific appointments. So, if a patient subsequently has a change in condition, such as pregnancy, then you have to submit a new form. Each user has to register (which does not facilitate common access within the same organization or other collaborating organizations to see if the transportation benefit has already be filed for the same request or of the status of such request).*
- *Streamlining eligibility processes across multiple public programs like MassHealth, nutrition programs, etc. would be an effective way to address social factors.*
- *Housing insecurity and homelessness are significant factors, which often face systemic barriers and waiting lists for assistance.*
- *Two-way data sharing is a critical component to the success of partnerships between health care providers and community-based organizations. We recommend the state address the existing barriers through available levers to create policy change that will enable bi-directional data sharing between providers and community-based organizations in order to track referral outcomes and follow-up.*
- *A state role is recommended in supporting greater access to short-term respite care capacity in Massachusetts, as a means of provided community-based alternatives to skilled nursing facility care for patients, particularly those with social acuity and co-occurring behavioral health needs, who require an enhanced level of support after hospital discharge.*

AGO Pre-Filed Testimony Questions

1. For provider organizations: please submit a summary table showing for each year 2014 to 2017 your total revenue under pay for performance arrangements, risk contracts, and other fee for service arrangements according to the format and parameters reflected in the attached **AGO Provider Exhibit 1**, with all applicable fields completed. To the extent you are unable to provide complete answers for any category of revenue, please explain the reasons why. Include in your response any portion of your physicians for whom you were not able to report a category (or categories) of revenue.

AGO Provider Exhibit 1 incorporates total revenue for CHA's Hospital and Physician network. In some circumstances, risk arrangements may not incorporate both our hospital and physicians, and data represents an aggregated result of these contracts. The data is supplied in total (not apportioned by HMO and PPO), as systems are not presently in place to track to this level. The data exhibits the level of reporting in place during a particular fiscal year. Therefore, conclusions should not be drawn about the relative changes in reimbursement or shifts in payer-related activity year-over-year.

2. Chapter 224 requires providers to make price information on admissions, procedures, and services available to patients and prospective patients upon request.
 - a) Please use the following table to provide available information on the number of individuals that seek this information.

Health Care Service Price Inquiries CY2016-2018			
Year		Aggregate Number of Written Inquiries	Aggregate Number of Inquiries via Telephone or In-Person
CY2016	Q1	17	All Phone: Tracking began February 2016
	Q2	46	All Phone
	Q3	64	All Phone
	Q4	49	All Phone
CY2017	Q1	43	All Phone
	Q2	82	All Phone
	Q3	102	All Phone
	Q4	76	All Phone
CY2018	Q1	95	All Phone
	Q2	86	All Phone
TOTAL:		660	All Phone

- b) Please describe any monitoring or analysis you conduct concerning the accuracy and/or timeliness of your responses to consumer requests for price information, and the results of any such monitoring or analysis.

CHA has created a price quote line within its Financial Assistance Department which is promoted both externally, via the CHA website, and internally, as a resource for patients to request a price quote for all services at CHA. CHA Customer Service staff manage the request internally, utilizing a standardized price quote request form to expedite the process in a timely fashion. Coding staff perform the necessary research and evaluation, following CHA and regulatory policies and procedures, and then send the information back to Customer Service staff to complete and communicate back to the patient. The patient is called with the information and sent a confirmation letter, or the letter is e-mailed based on patient preference, once the request is completed. The standard letter format includes both the pricing for the requested services and a link to the website of the payer for the patient to access information related to the required allowed amount by their insurance company.

A tracking system was established in February of 2016 to maintain a record of requests received and to monitor the turnaround time for such requests. Copies of confirmation letters are also scanned and kept on file for future reference. The average rate of turnaround within 48 hours is 97% of total requests.

- c) What barriers do you encounter in accurately/timely responding to consumer inquiries for price information? How have you sought to address each of these barriers?

Obstacles to providing price quotes usually relate to a lack of accuracy as to the particular request. The implementation of a standardized price quote request form and staff training has helped to improve service to patients in this area.

3. For hospitals and provider organizations corporately affiliated with hospitals:

- a) For each year 2015 to present, please submit a summary table for your hospital or for the two largest hospitals (by Net Patient Service Revenue) corporately affiliated with your organization showing the hospital's operating margin for each of the following four categories, and the percentage each category represents of your total business: (a) commercial, (b) Medicare, (c) Medicaid, and (d) all other business. Include in your response a list of the carriers or programs included in each of these margins, and explain whether and how your revenue and margins may be different for your HMO business, PPO business, and/or your business reimbursed through contracts that incorporate a per member per month budget against which claims costs are settled.

CHA is unable to complete this table because it does not have a validated cost accounting system in place at this time. While it may be possible to make estimates of the contribution margin by payer utilizing ratios from sources such as the Medicare cost report, these estimates would not be an accurate assessment of costs at the individual patient, and therefore aggregated payer, level. Given the level of assumptions necessary to develop this type of analysis, CHA has concerns that, even if it were able to submit information, the results would not be comparable across providers. We have provided the margin data at the total provider level. Please find linked the Center for Health Information and Analysis Acute Hospital Financial Performance Trends for CHA for FYs 2013 through 2017, which can be accessed at <http://www.chiamass.gov/assets/Uploads/mass-hospital-financials/2017-annual-report/five-year-trend/cambr-ha.pdf>.

CHA's high government payer mix and lower commercial insurance payer mix makes adequate commercial insurer reimbursement of critical importance to carrying out its patient care mission to care for all.

The data below from the Center for Health Information and Analysis's databook (April 2018 Provider Price Variation in the Massachusetts Commercial Market report) highlights this observation. The commercial health plans pay CHA far below the payer-specific average hospital relative prices and a minimum payment level of 90% of the statewide average relative price, which we seek to support thriving local health care access and investments.

CHIA Calendar Year 2016 Payer - Specific Relative Price - Acute Hospitals

Source: CHIA Relative Price Databook (April 2018)

Hospital	Payer-Abbrev.	Insurance Category	Product Type	Data Year	Blended RP	Blended RP Percentile (100 = high)
Cambridge Health Alliance	Aetna	Commercial (self and fully insured)	All Product Types Combined	2016	0.63	6
Cambridge Health Alliance	BCBS	Commercial (self and fully insured)	All Product Types Combined	2016	0.84	21
Cambridge Health Alliance	CeltiCare	Commercial (self and fully insured)	All Product Types Combined	2016	---	---
Cambridge Health Alliance	Cigna East	Commercial (self and fully insured)	All Product Types Combined	2016	0.52	18
Cambridge Health Alliance	Cigna West	Commercial (self and fully insured)	All Product Types Combined	2016	1.10	78
Cambridge Health Alliance	Fallon	Commercial (self and fully insured)	All Product Types Combined	2016	0.89	54
Cambridge Health Alliance	HPHC	Commercial (self and fully insured)	All Product Types Combined	2016	0.75	15
Cambridge Health Alliance	NHP	Commercial (self and fully insured)	All Product Types Combined	2016	0.79	32
Cambridge Health Alliance	Network Health	Commercial (self and fully insured)	All Product Types Combined	2016	0.60	4
Cambridge Health Alliance	Tufts	Commercial (self and fully insured)	All Product Types Combined	2016	0.73	14

- b) For 2017 only, please submit a summary table for your hospital or for the two largest hospitals (by Net Patient Service Revenue) corporately affiliated with your organization showing for each line of business (commercial, Medicare, Medicaid, other, total) the hospital's inpatient and outpatient revenue and margin for each major service category according to the format and parameters provided and attached as **AGO Provider Exhibit 2** with all applicable fields completed. Please submit separate sheets for pediatric and adult populations, if necessary. If you are unable to provide complete answers, please provide the greatest level of detail possible and explain why your answers are not complete.

Please see the response to question 3.a) above.