Mandated Benefits Review by the Pennsylvania Health Care Cost Containment Council

House Bill 1105
Bleeding Disorders

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EXECUTIVE SUMMARY

The Pennsylvania Health Care Cost Containment Council is required to review current or proposed mandated health benefits, on request of the executive and legislative branches of government, [Section 9 of Act 14 of July 17, 2003]. Act 14 places the burden of providing documentation on supporters and opponents of proposed mandated benefits. The Council's review determines if sufficient evidence is available for a formal Mandated Benefits Review Panel of outside experts to review the studies submitted.

Any panel must (1) review the documentation submitted by opponents and proponents, and (2) report to the Council on whether the documentation is complete with regard to the eight information categories described in Act 14, whether the research cited meets professional standards, whether all relevant research has been cited in the documentation, and whether the conclusions and interpretation in the document are consistent with the data submitted.

This report summarizes the documentation submitted in regard to House Bill 1105, which would mandate the coverage of certain services for bleeding disorders, some by specific providers, by individual and group health insurance policies.

Key information on the eight categories of required information includes:

1. The extent to which the proposed benefit and the services it would provide are needed by, available to and utilized by the population of the Commonwealth.

The language of the bill refers to individuals with "bleeding disorders," broadly defined. About 1,700 individuals are affected by hemophilia in the state; it is unclear how many of these would be covered by the mandated benefits. About 75,000 people with Von Willebrand Disease covered by employer-sponsored insurance are estimated to be eligible for services mandated by the bill. Information on availability and utilization of services is conflicting and unclear.

2. The extent to which insurance coverage for the proposed benefit already exists, or if no such coverage exists, the extent to which this lack of coverage results in inadequate health care or financial hardship for the population of the Commonwealth.

Conflicting information was supplied about whether services that are already being provided under current coverage sources are adequate or inadequate.

3. The demand for the proposed benefit from the public and the source and extent of opposition to mandating the benefit.

Proponents argued for the bill establishing an urgently needed standard of care for hemophilia treatment. Opponents argued that the scope of HB 1105 is too broad and raised concerns about specific provisions of the bill as well as its overall impact on costs.

4. All relevant findings bearing on the social impact of the lack of the proposed benefit.

In addition to documentation discussed in item (3) regarding the need for a standard of care, proponents argued that the lack of screening for Von Willebrand's Disease leads to adverse consequences, such as unnecessary hysterectomies.

5. Where the proposed benefit would mandate coverage of a particular therapy, the results of at least one professionally accepted, controlled trial comparing the medical consequences of the proposed therapy, alternative therapies and no therapy.

Documentation was supplied about the efficacy of hemophilia treatments supplied by specialized Hemophilia Treatment Centers (HTCs).

6. Where the proposed benefit would mandate coverage of an additional class of practitioners, the results of at least one professionally accepted, controlled trial comparing the medical results achieved by the additional class of practitioners and those practitioners already covered by benefits.

Documentation is discussed under item (5).

7. The results of any other relevant research.

Documentation was supplied on the efficacy of specialty home pharmacies, costs related to interventions focusing on “target joint” complications, and on the costs of unnecessary hysterectomies.

8. Evidence of the financial impact of the proposed legislation, including at least:
   (A) The extent to which the proposed benefit would increase or decrease cost for treatment or service.
   (B) The extent to which similar mandated benefits in other states have affected charges, costs and payments for services.
   (C) The extent to which the proposed benefit would increase the appropriate use of the treatment or service.
   (D) The impact of the proposed benefit on administrative expenses of health care insurers.
   (E) The impact of the proposed benefits on benefits costs of purchasers.
   (F) The impact of the proposed benefits on the total cost of health care within the Commonwealth.

Proponents argued that savings would occur because of improved health outcomes. Opponents argued that the bill’s provisions would limit the free-market mechanism and increase both the prices and overall cost of blood factor products and hemophilia services. Specific data on costs, when supplied, were not accompanied by documentation explaining and justifying methods for determining such costs. No information was supplied regarding the impact on total health care costs.

REVIEW OF HOUSE BILL 1105

Overview of Bill

House Bill 1105 would require individual and group health insurance policies covering bleeding disorders provide certain services, some by specific providers.

The bill specifies that health care insurers contract with any pharmacy that provides blood-clotting products as prescribed by the covered person's physician; that they offer and pay for all FDA-approved brands of blood-clotting products, as prescribed by the treating physician, for inpatient care, outpatient care, and the home treatment of bleeding disorders.

Insurers will be required to pay for services provided to individuals with bleeding disorders by State-recognized hemophilia programs (Hemophilia Treatment Centers) that include clinical laboratory services, blood-clotting products and physicians' fees.

Insurers would be required to offer patients at least three full-service home care pharmacies that comply with twelve qualifications; additionally, a patient with hemophilia could obtain certain services from any other participating pharmacy or from the 340B program affiliated with the patient's State-recognized hemophilia program.

Physicians would be required to request medical screenings for Von Willebrand Disease for any individual considering an invasive uterine procedure. The screening would have to be performed at a laboratory associated with a State-recognized hemophilia program and insurers would be required cover the screening as well as any physicians' fees and diagnostic lab services.

Mandated Benefits Review Process

PHC4's enabling legislation, Act 89 of 1986 (as re-authorized by Act 34 of 1993 and Act 14 of 2003), provides that PHC4 review current law or proposed legislation regarding mandated health benefits when requested by the executive or legislative branches of government. Rep. Anthony DeLuca, Chairman of the House Insurance Committee, has requested that PHC4 review the provisions of House Bill 1105.

A notice was published in the *Pennsylvania Bulletin* on December 15, 2007, requesting that interested parties submit documentation and information pertaining to House Bill 1105 to PHC4.

Letters also were sent to potentially interested individuals and organizations informing them of the pending review and inviting them to submit information pursuant to the notice. Following the initial comment period ending February 15, 2008, interested individuals and organizations were notified of opportunities to examine the responses received and submit a second round of comments. Final submissions were due to PHC4 on March 31, 2008. The Pennsylvania Department of Health and the Insurance Department were notified of the review and received a copy of the submissions. A list of the submissions received and a copy of the bill are attached.

Act 14 provides for a preliminary PHC4 review to determine if the documentation submitted is sufficient to proceed with the formal Mandated Benefits Review process outlined in the Act. This formal process consists of convening a review panel with five members with expertise in specified fields to review the documentation submitted by proponents and opponents. This report summarizes whether the material addresses each of the categories of analysis.

Analysis of Documentation Submitted by Opponents and Proponents in Response to the Eight Categories Required by Act 14, Section 9

I. The extent to which the proposed benefit and the services it would provide are needed by, available to and utilized by the population of the Commonwealth.

Affected population

Proponents' submissions cited an estimate of 1,700 individuals in the Commonwealth having hemophilia[1] of varying severity. Although HB 1105 is referred to as the "Hemophilia Standards of Care Act," the bill also would mandate benefits for individuals affected by other "bleeding disorders … which result in uncontrollable bleeding or abnormal blood clotting"[2] (e.g., Von Willebrand Disease).

It is not clear how many of the 1,700 individuals with hemophilia would be exempt from HB 1105 because of ERISA[3] pre-emption of state insurance laws on self-funded benefit plans. Although about 50 percent of privately insured individuals in the state are believed to be subject to ERISA pre-emption, the costs of the disorder may have led families to obtain coverage disproportionately through other sources than private insurance.

Studies stated that Von Willebrand Disease (VWD) occurs in approximately 1 to 2 percent of the general population and equally affects both genders[4]. If the high estimate (2 percent) were applied to the Commonwealth's population, approximately 250,000 individuals may have VWD in Pennsylvania.[5] PHC4 staff estimated 75,000 individuals with VWD in private sector employment-based plans would be affected by the bill.[6]

Proponents and opponents disputed whether HB 1105 applies to Medical Assistance and Medicare insurance policies in the Commonwealth. The Pennsylvania Chapters of the National Hemophilia Foundation (NHF) stated that the "legislation does not apply to Medicaid or Medicare health insurance plans …"[7] However, other respondents assumed that these programs would be subject to the mandated requirements.

Respondents did not provide any specific estimates for the number of individuals with bleeding disorders other than hemophilia and VWD. Neither proponents nor opponents supplied estimates of the total number of individuals covered by the bill's provisions.

Availability

Proponents and opponents agreed that the bill is a not a mandate in the sense that it requires insurance policies to provide offers of coverage to individuals with bleeding disorders. Rather, the bill mandates a number of specific benefits, including the services of specific providers, which insurance policies must cover if they offer coverage for bleeding disorders.

Proponents' Submissions: In a letter to PHC4, the Delaware Valley Chapter of the National Hemophilia Foundation characterized it as "Standards of Care legislation" and stated: "HB 1105 is not a mandate for insurance coverage for the 1,700 Pennsylvanians affected by hemophilia, as all insurers in Pennsylvania currently cover, to some degree, health care expenses for the treatment of hemophilia."(Letter dated Jan. 1)

"Generally speaking, there currently exists insurance coverage for persons with hemophilia; however, that coverage varies widely in Pennsylvania—from fairly comprehensive to inadequate. A substantial percentage…have inadequate insurance coverage…and this has compromised their health care. Because the cost of treatment for a person with severe hemophilia is very high, when the patient's insurer denies coverage for any aspect of essential health care, the patient usually lacks the financial means to shrug off the coverage denial and self-pay the required health care services."

Proponents provided statements from hematologists as well as reports from the hemophilia community to argue that bleeding disorders require specialized treatments and services which many insurers do not adequately cover. In addition, they argued that insurance policies should be required to cover patient services received from the seven state-recognized hemophilia programs, also known as Hemophilia Treatment Centers (HTC). Proponents argued that such treatments are cost-effective since services mandated by HB 1105 would reduce costs for hospitalization, emergency-room visits and emergency factor replacement therapy.

Documentation from Pennsylvania Chapters of the National Hemophilia Foundation (NHF) represents key arguments made by proponents of HB 1105:

- "[S]ome insurance companies and their pharmacy benefit managers have tried to limit patient access to the full range of medically necessary blood clotting therapies … [and] have required patients to utilize a single, 'preferred' blood clotting product for the treatment of hemophilia." The Foundation argued that because blood clotting therapies are not therapeutically equivalent in all patients, and no generic products are available for the treatment of hemophilia, blood clotting factor therapies should not be restricted. "Without optimal blood clotting therapies, individuals with hemophilia will bleed into joints and tissues, which may result in lifelong pain and permanent disability."

- "Insurance companies and pharmacy benefit managers have moved patients with bleeding disorders from full-service home care pharmacies to mail order pharmacies that do not offer skilled, home supportive services…"

- "A screening requirement [for von Willebrand Disease (VWD)]…will prevent needless invasive surgeries. .. [NHF] estimates that approximately 30,000 women annually [nationwide] have hysterectomies due to undiagnosed von Willebrand Disease. A hysterectomy for someone with [VWD] may not be necessary and it does not address the cause of the excessive bleeding…"

- Proponents argue that highly specialized tests for individuals with hemophilia and von Willebrand Disease should be performed in a coagulation laboratory, associated with seven state-recognized hemophilia programs.[8]

Utilization

The NHF and other proponents stated that "more than 75 percent of persons with hemophilia who reside in Pennsylvania receive medical care from a state-recognized hemophilia program." However, though 75 percent of Pennsylvania patients with hemophilia use Hemophilia Treatment Centers, it was not clear (1) what proportion of patients' total services are received from HTCs, and (2) whether this proportion applies to individuals in plans subject to the mandate.

II. The extent to which insurance coverage for the proposed benefit already exists, or if no such coverage exists, the extent to which this lack of coverage results in inadequate health care or financial hardship for the population of the Commonwealth.

Opponents' Submissions: Opponents of HB 1105 argued that adequate care is already provided by their health plans' benefit designs. Independence Blue Cross (IBC) stated:

> "IBC already covers the treatment of hemophilia and includes all FDA-approved blood-clotting products in our formulary. In addition, most hemophilia care in our service area is already concentrated in [the] regional government-approved hemophilia centers cited in HB 1105…In 2007, IBC spent more than $21.5 million for antihemophilic drugs on behalf of 101 members with hemophilia and other coagulation defects—this figure is based only on those members with drug costs of $10,000 or more a year. The average amount paid by IBC [on these types of drugs] …for each member of this group was more than $214,000—with the highest amount spent for a single patient at $3.66 million."

BlueCross of Northeastern Pennsylvania (BCNEPA) currently "includes all FDA-approved blood clotting products on the plan's formulary"[9] and stated:

> "We are unaware of any major obstacles to accessing covered health benefits for bleeding disorders or of routine coverage denials for such services. BCNEPA currently has six members who access hemophilia benefits.… [For the pharmaceutical costs alone] BCNEPA's six patients use approximately $1.9 million in products collectively—or an average of $317,000/yr each…"

Highmark stated:

> "Highmark currently provides coverage for hemophilia and congenital blood disorders based on a member's benefit plan. In 2006, 101 customers received hemophilia treatment services at a cost of $15 million.…"
>
> "Highmark's medical policy for the coverage of blood clotting factors includes: Blood clotting factors for hemophilia patients with any of the following diagnoses may be covered to control bleeding: Factor VIII deficiency (classic hemophilia); Factor IX deficiency (also termed plasma thromboplastin component (PTC) or Christmas factor deficiency); and Von Willebrand Disease."
>
> "Highmark currently provides coverage for Von Willebrand Disease testing if deemed medically necessary, e.g., surgery is being considered as a treatment option."

AmeriHealth Mercy Health Plan and Keystone Mercy Health Plan stated: "Currently, Keystone Mercy Health Plan is the largest Medicaid managed care organization in the state and serves over 75% of the hemophilia population enrolled in Pennsylvania's HealthChoices program …" The plans went on to contend that, as capitated plans are at financial risk for all medical, hospital, pharmacy, and ancillary healthcare costs, "it would be imprudent…to be 'penny-wise' by encouraging or mandating the use of low cost or substandard pharmaceuticals or medical services that resulted in inferior or substandard outcomes, and 'dollar-foolish,' by absorbing excessive hospitalization, medical, and pharmacy costs associated with providing inappropriate drug therapy or associated health care services. We…have established a comprehensive hemophilia case management program that teams a clinical pharmacist with a dedicated

hemophilia nurse case manager to coordinate the overall medical and drug therapy needs for our members …"

Financial hardship.

Neither proponents nor opponents provided any specific data regarding the extent of financial hardship for individuals with bleeding disorders in the Commonwealth. Proponents referred to the cost of services (e.g., $120,000 for emergency factor replacement therapy). However, it was not clear what share of these costs that patients and/or families were paying out of pocket.

III. The demand for the proposed benefit from the public and the source and extent of the opposition to mandating the benefit.

Proponents' Submissions: PHC4 received submissions from the Pennsylvania Chapters of the National Hemophilia Foundation (including a large number of letters and statements supporting HB 1105), CSL Behring, and Rep. Lawrence H. Curry, Pennsylvania House of Representatives.

Proponents argued there was an urgent need for a minimum "standard of care" for individuals with bleeding disorders. They submitted expert statements and personal reports attesting that bleeding disorders such as hemophilia are not widely understood, even within the physician community; that specific support services such as in-home nursing and infusion therapies can provide superior medical and cost outcomes (see discussion in Sections V and VII); that hemophilia patients must have the right to services provided by HTCs and that insurance policies should not be able to limit any treatment deemed medically necessary by a patient's treating physician. (See also Section I.)

The Pennsylvania Chapters of the NHF stated that:

"The standards reflect the collective wisdom and experience of medical, scientific and government persons knowledgeable about hemophilia...[including] health care practitioners employed at the seven state-recognized hemophilia programs; the epidemiological studies performed by the Centers for Disease Control (CDC); and the recommendations of the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation."(March 28 letter to PHC4, p. 4)

"Most patients with severe hemophilia receive treatment at one of the seven state-recognized hemophilia programs. Generally, insurance companies do allow patients to be treated at one of the hemophilia programs; however, there are significant problems with access to FDA approved blood clotting factors, access to the diagnostic coagulation laboratories, and access to full-service home care pharmacies which are essential to the well being of many patients. The Pennsylvania Chapters of the National Hemophilia Foundation have received hundreds of complaints from patients limited by insurance companies from receiving one or more of the elements of essential medical treatment."

Opponents' Submissions: PHC4 received submissions from the following organizations in opposition to the legislative proposal: AmeriHealth Mercy Health Plan and Keystone Mercy Health Plan, BlueCross of Northeastern Pennsylvania, Highmark, Independence Blue Cross, the Insurance Federation of Pennsylvania, the Pennsylvania Chamber of Business and Industry, and Wolf Block Government Relations (on behalf of AFLAC).

While not specifically opposing the mandates contained in HB 1105, the American Family Life Assurance Company of Columbus (AFLAC) suggested that supplemental insurance policies be excluded from the bill. AFLAC argued that its supplemental policies are not intended to be substitutes for comprehensive major medical health insurance.

Opponents argued that the scope of HB 1105 is too broad and raised concerns about not only specific provisions of the bill but its overall impact. Opponents argued that HB 1105 legislating a standard of care to be delivered by insurers and providers would set a dangerous precedent. The Insurance Federation of Pennsylvania stated, "[T]he idea of legislating medical practice and writing current medical standards into law is bad public policy." (Letter to PHC4, Feb. 15, p. 7). BCNEPA argued that "a legislative body should not place standards of care in statute. With ongoing advancements in medical care, such standards or practices can change rapidly." IBC stated: "The standards of medical care are constantly changing with new drugs, equipment, procedures, and methodology. IBC believes that the medical profession should determine standards of care, not the State Legislature."

HB 1105's legally established "standard of care," opponents argued, would not only mandate specific benefits but allow the patient along with physicians to authorize high-cost drugs and services and choose providers without restriction by the health plan. This would undermine the cost-containment tools used by health plans, and give bleeding disorders a unique status in law and in health coverage that no other medical condition currently enjoys.

AmeriHealth Mercy Health Plan stated: "If Pennsylvania passes legislation giving unlimited/unrestricted prescribing authority to providers treating individuals with hemophilia, it will only provide fuel for other special interest groups, and the pharmaceutical industry which often backs them, to demand equivalent prescribing authority for the groups they represent."

The Insurance Federation of Pennsylvania argued: "[U]nwinding managed care techniques for one group of afflicted citizens is a short road to destroying a very valuable cost control regime. If every single interest group insisted on unwinding policy controls and policies so that all care decisions were left with providers, insurers would have little control over their major costs."

BCNEPA stated: "BCNEPA questions the need for legislation that would grant special status—by stripping away an insurer's ability to manage quality care—to hemophilia and other bleeding disorders and the providers of these services, especially when such services are already widely covered under existing health insurance plans. "

Regarding the requirement that any "physician licensed in this Commonwealth to provide obstetrical and gynecological services shall request a medical screening for Von Willebrand Disease and other bleeding disorders" [prior to invasive uterine surgery] which "shall be performed at a clinical coagulation laboratory associated with a State-recognized hemophilia program" (HB 1105, Section 7), BCNEPA stated that it opposes placing "a requirement on the physician community."

Opponents argued that HB 1105 would grant special status in law to one specific set of providers (HTCs) in addition to giving providers generally increased negotiating leverage in determining the costs/prices of services. Furthermore, opponents argued that the pharmacy provisions would give patients the right to choose "any willing provider," and, along with the terms of payment provisions in Section 4, would allow providers to determine prices and eliminate any savings that health plans obtain from selective contracting. Moreover, they argued the law would effectively increase providers' (drug manufacturers, HTCs and full-service

home care pharmacies) profits. (For further discussion on possible cost and pricing outcomes connected with the bill, see Section VIII).

IBC stated:

> "HB 1105 will discourage competitive drug pricing. Many high quality vendors who compete for IBC's business nationally supply blood factor… Eliminating the ability to make them compete in order to lower costs would, in fact, increase costs to hemophiliacs and others with factor deficiencies, while offering no guaranteed increase in quality … Eliminating this sound and accepted business practice would provide no additional benefit to consumers and employers, but it would increase their costs since pricing would no longer be established on a competitive basis. If HB 1105 passes, we will have the same blood factor at a higher price. Why would a manufacturer, wholesaler or pharmacy compete effectively when the basic, responsible principles of effective buying and management are overridden by legislation? Worse yet, HB 1105 provides a precedent to create the same waste and poor economic consequences in other therapeutic areas where consumers and their employers are already pressed to afford their current health care."

According to BCNEPA:

> "The mandates [in the bill] will not increase the quality or accessibility of health care in Pennsylvania, however, it is certain that implementation of this open-ended mandate that also contains an 'any willing provider' provision will increase the cost of health care coverage in the Commonwealth…Although Pennsylvania does not currently have an 'any willing provider' law, this legislation would basically create such a law for those who treat bleeding disorders…Health insurers [would be required to] … **accept all payment requests** [emphasis in original] for blood clotting products, ancillary infusion equipment and home nursing services submitted by full-service providers in compliance with the act. The provision undermines the insurer's ability to utilize provider contracting, claims administration, medical management and fraud prevention tools in order to maximize benefits for the consumer."

Opponents raised concerns that any cost increases would not only affect payors but hemophilia patients themselves, who may face lifetime caps on the amount of coverage under some insurance policies.

Highmark noted: "Although Highmark fully respects the relationship between patient and physician, and believes that the majority of providers and agencies act in each patient's best interest, insurers are in a unique position to work with providers and advocate appropriate standards that have been shown to improve overall medical care. If Highmark did not require providers to adhere to such standards, patients could be faced with unanticipated health care costs or they could reach their lifetime benefit cap much sooner than they expected."

Opponents argued that a more narrow approach could remedy any deficiencies in care for hemophilia, rather than enact legislation that would likely have adverse, unintended consequences. Highmark stated that three states have adopted hemophilia "advisory board" laws (see also Section VIII.B.), explaining that "The boards created by these statutes have the responsibility of examining matters related to access to care and adequate health insurance coverage for individuals with hemophilia and other bleeding disorders. In addition to reporting to their respective state legislatures, they also have an advisory role, which includes notifying various state agencies regarding policies that affect individuals with hemophilia and other bleeding disorders. Before the General Assembly adopts House Bill 1105, it should consider

examining the 'advisory board' option as an alternative to a health insurance mandate for hemophilia."

Opponents pointed out that some mandates have unintended consequences that pit the interests and medical coverage of some citizens and some members within a given health plan against those of others. Highmark stated: "[W]e reiterate our commitment to understanding the devastating effects that hemophilia and other congenital bleeding disorders may have on an individual as well as their need for highly specialized treatment. However, we must also meet the needs of our other members that may be suffering with a debilitating illness. They, too, require and deserve access to high quality health care."

IBC stated that "this proposed mandate has the potential of further eroding coverage in the small group market … With each 1 percent increase in health insurance premiums, 14,000 Pennsylvanians lose their coverage. … The mandates imbedded in HB 1105 will not increase the quality of care or access to blood-clotting products. It would instead place a heavier financial burden on small employers who are least able to shoulder the cost."

Additionally, opponents outlined several general arguments about the net impact of mandated health benefits.

- ***Mandates, in general, increase total health care costs***

  Opponents argued that mandates increase premium costs, reduce health coverage for some individuals, and may increase levels of uninsurance. The opponents explain how large employers become self-insured under terms of ERISA to avoid mandates. Businesses too small to self-insure face increased insurance premiums. These employers pass on premium costs to their employees, through increased contributions toward health care coverage and/or reducing wage or salary costs. Some employees may cease to participate in insurance because of the higher contributions and become uninsured. Likewise, employers may respond to increased compensation costs by reducing workforce levels.

- ***Mandates must be considered in light of their cumulative impact***

  Opponents argued that, although one individual mandate may have minimal cost implications, taken together with other mandates, the impacts are substantial. Two studies were cited. The Council for Affordable Health Insurance, in its *Health Insurance Mandates in the States 2008,* found that the collective impact of mandates increased the costs of basic coverage from slightly less than 20% to more than 50%, depending on the state. *Mandated Benefits Laws and Employer-Sponsored Health Insurance (Health Insurance Association of America, January 1999)* estimates that as many as one in four people are uninsured because of the cost of state health insurance mandates.

IV. All relevant findings bearing on the social impact of the lack of the proposed benefit.

Proponents supplied a number of studies and background materials on the importance of medical screening for Von Willebrand Disease and other bleeding disorders.[10] Women with undiagnosed[11] Von Willebrand Disease who are having excessive menstrual bleeding are sometimes given hysterectomies to control the condition. Proponents cited a national CDC estimate of 30,000 unwarranted hysterectomies performed annually and argued that mandated

screening for VWD and other bleeding disorders prior to invasive uterine procedures would reduce such unneeded surgeries and aid in identifying bleeding disorders in women.

V. Where the proposed benefit would mandate coverage of a particular therapy, the results of at least one professionally accepted, controlled trial comparing the medical consequences of the proposed therapy, alternative therapies and no therapy.

To support coverage of HTC services, proponents supplied studies and background materials on patient outcomes associated with using HTC physicians and services.

A study[12] based on surveillance data collected on 2,950 individuals from six states during 1993-95 compared the relative mortality risk of hemophilia patients receiving services from HTCs at least once during the study period to patients not receiving such care. After adjusting for risk characteristics, such as age, ethnicity, hemophilia type, disease severity, insurance type, inhibitor status, liver disease, HIV serostatus, and AIDS, the study found that medical care provided by HTCs was strongly associated with reduced mortality. Persons who had received care in HTCs during the study period were 40 percent less likely to die than those who had not.[13] HTC patients were more likely than non-HTC patients (61 compared to 25 percent, $p < .001$) to use home factor-inclusion programs coupled with professional support, which facilitate early treatment of bleeding episodes. The study did not directly compare the relative risk of mortality based on whether the patients utilized home factor-infusion therapy, independently of HTC affiliation.

A follow-up surveillance study by the same researcher compared hospitalization for bleeding complication (HBC) rates during 1993-1997 on 2,650 males from six states having varied risk profiles. The study found that, after adjusting for age, ethnicity, disease severity, factor usage, and inhibitor status, home-based infusion therapy combined with HTC care was most likely to avoid an HBC. "[After appropriate adjustments]… [P]atients using both home therapy and HTCs had the longest HBC-free intervals, whereas those who used neither had the shortest. Patients using either home therapy or HTCs alone had intermediate HBC-free time intervals."[14]

Additionally, "[F]indings suggest that the individual effects of care in HTCs and home therapy on HBC rates are independent of one another… HTC care most likely reduces HBC rates through extensive preventive education provided to patients." The study also found that individuals with private commercial insurance had a statistically significantly lower relative risk for an HBC compared to other types of patients, after adjustment for other risk determinants.15 The study offered a caveat, because of data-collection limitations, "[W]e may have underestimated the protective effective of home therapy on HBC."

(In Section VII, specialty home care pharmacies report their hospitalization rates for bleeding complications.)

VI. Where the proposed benefit would mandate coverage of an additional class of practitioners, the result of at least one professionally accepted, controlled trial comparing the medical results achieved by the additional class of practitioners and those practitioners already covered by benefits.

See Section V.

VII. The results of any other relevant research.

Medical and cost outcomes associated with using specialty home care pharmacies. Proponents submitted materials that included case examples and data supplied by specialty home care pharmacies to support their argument that utilization of full-service home care pharmacies leads to both superior medical and cost outcomes.

OptionCare, a specialty home care pharmacy that supports HB 1105, supplied descriptive data (2006) comparing hospitalization rates for bleeding complications per 100 patient years (PYs) of hemophilia patients receiving care from OptionCare's own nurses and in-home services with sub-contracted (agency) nurses. The total number of patients in the comparison exceeded 500; the study population cared for by OptionCare nurses was 92.7 percent, and for the subcontracted-nurse care, 7.3 percent. It was not clear from the information provided whether the OptionCare study was based on scientifically controlled comparisons or how the cost estimates were derived.

OptionCare reported a hospitalization rate of 5.65 for its own nurses compared to the subcontracted/agency nurse rate of 36.5 and a "benchmark" rate of 21.2 admissions per 100 PYs based on the four-year study cited in Section V.[16] Extrapolating from the difference in hospitalization rates, OptionCare calculated that its nurses demonstrated a cost-savings of $1,162,500 compared to the benchmark-study rate and a cost-savings of $2,313,750 in comparison to subcontracted/agency-nurse care rate.

Additionally, OptionCare provided several case examples, based on 2006-07 data of one of its clients, showing how its management of factor utilization, assay audits, and continuous factor infusion program improved patient outcomes by decreasing emergency-room utilization and having fewer bleeds and produced cost-savings. OptionCare argued that the quality of its services and skill in managing costs were responsible for these cost-savings.

Proponents supplied a case example from another home-care pharmacy[17] of a 12 year-old male with Hemophilia A/Mild with Inhibitor, who had in the previous eight months, experienced serious target joint complications and received infusions primarily at an HTC and in an emergency room. The patient's factor utilization was reduced by 160,440 units (estimated at $200,550 cost-savings) as a result of home-based therapy and support in close collaboration with an HTC.

Costs associated with development of a target joint[18]: Proponents provided information from a home-care pharmacy[19] stating that the total cost of treating a patient with on-demand Factor VIII increased by 119 percent, from $17,798 before the complication to $38,882 in the year following development of a target joint; Factor VIII utilization accounted for 87 percent of the total cost in the year before target development and 93 percent in the year following the complication.

Cost savings associated with avoiding needless hysterectomies:
Proponents' Submissions: CSL Behring, in support of HB 1105, argued that the mandated screening requirements found in Section 7 of the bill would produce net claims cost-savings since "a hysterectomy is approximately $12-15,000 per procedure as compared to $200 for a VWD evaluation."

Opponents' Submissions: BCNEPA noted that "a typical panel can cost as much as $400 and the panel should be repeated up to three times in a suspected individual."[20]

Respondents did not provide specific data to evaluate these conflicting cost assessments. However, the net cost savings for the bill's screening mandate in the Commonwealth is not clear. The costs of medical screenings and associated HTC coagulation laboratory costs for all women who undergo such evaluations would have to be compared to reduced costs associated with estimated fewer hysterectomies to estimate the net financial impact.

VIII. Evidence of the financial impact of the proposed legislation.

A. The extent to which the proposed benefit would increase or decrease cost for treatment or service.

There was substantial disagreement about how HB 1105 could affect the market for hemophilia products and services and impact the costs of treatments and services.

Proponents' submissions: Proponents argued that cost savings would ultimately be realized through better medical outcomes (e.g., from more intensive utilization of the bill's mandated services such as in-home nursing and infusion therapies, which would result in fewer expensive emergency hospitalizations and procedures). (See also Section VII.)

The Pennsylvania Chapters of the NHF stated that HB 1105 would foster competition and that HB 1105 "does not mandate any specific amounts to be paid to health care providers. HB 1105 properly leaves the issue of insurance payments for medicine and health services to free market forces, so that insurance companies and providers may negotiate fees and costs as they currently do."

Opponents' submissions: Opponents argued that the bill's provisions would limit the free-market mechanism and increase both the prices and overall cost of blood factor products and hemophilia services. The Insurance Federation stated: "The bill decreases the ability of insurers to design coverages and programs and reduces the salutary effect of competition in the marketplace."

Opponents claim that health plans would lose bargaining power in negotiation with specialty pharmacies, HTCs, and other providers. Selective contracting and other cost-containment tools would be unavailable, since patients and their treating physicians can choose "any participating pharmacy," including HTCs. Treating physicians would be able to prescribe treatment without restriction; plans would not be able to refuse to make payment.

Additionally, opponents argue that the bill would lead to increases in the markup of clotting factor products from drug manufacturers, HTCs or full-service pharmacies. Factor product manufacturers could hold out for a higher price, knowing that the health plan is required by law to provide every brand of FDA-approved clotting factor product to its members. Specified providers for certain services (e.g., HTC coagulation laboratories) will make health plans "price takers," and give the provider the ability to increase profits. Furthermore, there might also be significant costs associated with patients' switching providers at will. The Mandated Benefits Committee, reviewing earlier drafts of this report, believed insufficient information was available on the potential impact of the bill on drug pricing.

IBC supplied an estimate that: "[T]he $21.5 million that IBC paid for drugs on this population will dramatically increase, perhaps as much as two-fold…HB 1105 will increase costs for our HMO/POS customers by approximately $427,000 annually. " It also argued that members, all of whom are currently required to use a designated provider for laboratory services, "would be covered for laboratory services at any laboratory if the treating physician deems the use of the hospital's clinical coagulation lab to be medically necessary."

BCNEPA estimated a doubling of costs for pharmaceutical costs alone for its six patient-members to "…$634,000 per year per patient. Such an increase can be devastating for a mid-size employer with an experience rated benefit plan. Since the disorder is familial (two of our 6 patients are siblings), the burden on any single employer—especially a small employer—can be even greater."

Highmark estimated that its network management cost containment achieves $1 million in savings annually (on total costs of $15 million annually for 101 patient-subscribers) and HB 1105 would likely eliminate these savings.

No specific information was provided on how these cost estimates were derived. A few opponents believed that they would face "minimal" cost changes as a result of HB 1105 because their plan coverages were already similar to the mandated requirements found in the bill. Actuarial and economic analysis would need more detailed data.

In addition to the conflicting cost-impact assessments made by respondents, several points of information should be noted. Many HTCs currently earn income that subsidizes their centers' programs by purchasing blood-clotting factor and related drugs at discount prices through the Federal 340B program[21] and reselling them to HTC patients[22]. The 340B discount specifies a maximum price that drug manufacturers can charge HTCs, often a substantial markdown from the average wholesale price (AWP) of drug products. This discount could give a competitive edge to HTCs over "full-service" home pharmacies in addition to any other advantages provided in the legislation. There are limitations on the prices HTCs can charge Medicaid and Medicare patients; these cost savings are not required to be passed on to private health plans. HTCs could gain additional revenue that could be used for other program needs or shared with the hospitals with which they are affiliated.

Other possibly unintended outcomes should be noted.[23] Health plans could respond to enactment of the legislation by excluding coverage for certain bleeding disorders, or offering differing pricing for group insurance depending on whether bleeding disorders are included or not. Plans could reclassify pharmaceutical products associated with bleeding disorders so that significantly higher copayments or percentage coinsurance are required from the plan member. HB 1105 does not require insurance policies to provide coverage for bleeding disorders but, rather, mandates benefits *if* they are covered in the policy.

B. The extent to which similar mandated benefits in other states affected charges, costs and payments for services.

Materials submitted cited five states with laws addressing insurance coverage for congenital bleeding disorders such as hemophilia**.** The Council for Affordable Health Insurance (CAHI) identified New Jersey (in 2000), and Virginia (in 1998) that have enacted laws mandating coverage for hemophilia and/or other congenital bleeding disorders.[24] They estimated that the mandates had raised insurance costs in those states by less than one percent.

Proponents' Submissions: The Pennsylvania Chapters of the NHF supplied letters from the Hemophilia Association of New Jersey and from an assistant commissioner in the State of New Jersey's Department of Health and Senior Services, stating that costs have not increased since New Jersey enacted Standards of Care legislation for hemophilia in 2000. No data was supplied to support these conclusions.

Opponents' Submissions: BCNEPA noted that Virginia "simply mandates coverage for hemophilia; it does not strip health insurers of their cost and quality controls as House Bill 1105 would."[25] Highmark stated: "In addition to the [two states'] mandates [above], three states have passed hemophilia 'advisory board' laws—Iowa [2007], Texas [2007] and Illinois [2007]…The boards…have the responsibility of examining matters related to access to care and adequate health insurance coverage for individuals with hemophilia and other bleeding disorders." No data was provided on the net health care cost impact of the laws in these states.

C. The extent to which the proposed benefit would increase the appropriate use of treatment or service.

Proponents argued that utilization of the mandated services by individuals with bleeding disorders would increase. Opponents argued that utilization of services covered in the bill would likely not increase since insurance policies are already providing an adequate standard of care for hemophilia. However, costs as well as the providers of those services could change. Respondents generally agreed that medical screening for VWD would increase as a result of HB 1105's mandate, because physicians would be required to order screenings prior to invasive procedures and use HTC coagulation laboratories for blood analysis.

D. The impact of the benefit on administrative expenses of health care insurers.

Respondents provided no information on how administrative expenses would be specifically affected, apart from other costs, which are outlined in Section VIII.A.

E. The impact of the proposed benefits on benefits costs of purchasers.

Respondents' arguments focused primarily on the cost and price changes of treatments and services as a result of HB 1105, assuming that net cost decreases or increases would ultimately translate directly into premium decreases or increases for purchasers of insurance policies covered by the bill.

Proponents' Submissions: Proponents argued that the bill's required "standard of care" would sufficiently improve medical outcomes that would, in turn, reduce utilization and thus costs for services associated with hospitalization, complications and emergency procedures, resulting in net cost savings for health plans. Proponents did not supply information on the effects of changing selective contracting practices or increasing screening rates.

Opponents' Submissions: Some opponents provided estimated expenditure increases for the purchasers of their insurance plans (see Section VIII.A.) although no respondent provided any specific premium-change estimates.

AmeriHealth Mercy and Keystone Mercy stated that HB 1105 "is a completely unfunded mandate and could cost the Commonwealth's Medical Assistance (Medicaid) program several millions of dollars at a time when this program is facing a steep deficit. This is based on the assumption that Managed Care Plans would no longer have the ability to as aggressively

negotiate contracts for required hemophilia products and services, and that reimbursement rates would revert to those that were experienced before current clinical and cost containment initiatives were implemented."[26] No further information specified how these estimates were derived.

F. The impact of the proposed benefits on the total cost of health care within the Commonwealth.

The submissions did not provide specific estimates for the overall impact of House Bill 1105 on health care costs within the Commonwealth. Additionally, it is not clear how the provisions of the legislation would impact the total cost of benefits related to bleeding disorders.

Submissions for House Bill 1105

1. AmeriHealth Mercy Health Plan and Keystone Mercy Health Plan
   - Letter and comments in opposition to House Bill 1105.

2. Blue Cross of Northeastern Pennsylvania
   - Letter and comments in opposition to House Bill 1105 and attached supporting documentation.

3. CSL Behring
   - Letter and comments in support of House Bill 1105.

4. The Honorable Lawrence H. Curry, Pennsylvania House of Representatives
   - Letter and comments in support of House Bill 1105 and attached supporting documentation.

5. Highmark
   - Letter and comments in opposition to House Bill 1105 and attached supporting documentation.

6. Independence Blue Cross
   - Letter and comments in opposition to House Bill 1105 and attached supporting documentation.

7. The Insurance Federation of Pennsylvania
   - Letter and comments in opposition to House Bill 1105.

8. The Pennsylvania Chamber of Business and Industry
   - Letter and comments in opposition to House Bill 1105.

9. The Pennsylvania Chapters of the National Hemophilia Foundation
   - Letter and comments in support of House Bill 1105 and attached supporting documentation.

10. Wolf Block Government Relations (on behalf of AFLAC)
    - Letter and comments regarding House Bill 1105

ENDNOTES

[1] HB 1105 (Section 3) defines "hemophilia" as a "human bleeding disorder caused by a hereditary deficiency of the Factor VIII, Factor IX or Factor XI blood clotting protein in human blood."

[2] The definition of "bleeding disorder" is found in Section 3. In addition to mandated screening benefits (Section 7), the bill requires in Section 6 that: "A health care insurer shall provide coverage for the following services provided to persons with bleeding disorders by a State-recognized hemophilia program: (1) Physician services (2) Blood clotting products … [and] (3) Clinical laboratory services …". Also, see Section 4 (2), which states: "A health insurer shall provide payment for blood clotting products as prescribed by the treating physician for in-patient care, out-patient care and the home treatment of bleeding disorders."

[3] The federal Employee Retirement Income Security Act of 1974 (ERISA).

[4] Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation Recommendation (Document) #173, October 2006.

[5] Based on the U.S. Census Bureau's Current Population Survey, 2007 Annual Social and Economic Supplement for Pennsylvania.

[6] This estimate is based on the assumed 2 percent of the individuals enrolled in employment-based health plans in Pennsylvania (7,894,000) multiplied by the proportion in fully insured plans subject to the mandate (.474) [see Table II.B.2.b (2005) of the Agency for Healthcare Research and Quality's 2005 Medical Expenditure Panel Survey, Insurance Component.]

[7] Letter to PHC4, March 28, p. 9.

[8] Quoted directly from fact sheets and other background material provided by the National Hemophilia Foundation.

[9] BCNEPA Letter to PHC4, Feb. 14, p. 5.

[10] Excessive bleeding, generally defined in supplied background materials as more than 80 mL of blood loss during the menstrual cycle.

[11] Proponents supplied a number of expert statements from hematologists and others stating that many physicians are not sufficiently familiar with coagulation disorders, which are complex and require specialized training to diagnose and treat.

[12] Soucie, J. Michael, Nuss R., Evatt B. et al. Mortality Among Males with Hemophilia: Relations with Source of Medical Care, *Blood* 2000; 96: 437-442.

[13] *Ibid*, p. 440.

[14] Soucie, J.M., Symons, J., et al."Home-based infusion therapy and hospitalization for bleeding complications among males with hemophilia." Hemophilia 2001; 7: 198-206 (Quote from p. 202).

[15] *Ibid*, p. 202.

[16] The benchmark study cited by OptionCare: Soucie, J.M., Symons, J., et al."Home-based infusion therapy and hospitalization for bleeding complications among males with hemophilia." Hemophilia 2001; 7: 198-206.

[17] It was not entirely clear from the material which home-care pharmacy handled the case and supplied the data.

[18] Target joints, according to background material supplied by proponents, are the sites of recurrent bleeds, defined by the CDC as 4 or more bleeds in a particular joint within a 6-month period or 20 or more bleeds in the same joint within any period of time. Most adults with hemophilia have several target joints, which are often located in their knees, ankles and elbows. If not treated, a bleeding episode may lead to further bleeding episodes, more continuing bleeds, increased pain, swelling, and limitation of joint mobility and long-term joint damage as well as increased factor usage and higher total costs of treatment.

[19] FactorCare, which cited the following sources as the basis of the cost figures: *Journal of Pediatrics* 2004, 145: 628-34, and *Haemophilia* 2002; 8: 217-22.

[20] In support of this datum, BCNEPA cites: Mortimore, Wendy, M.D. "Screening for von Willebrand Factor Disease," *Pediatrics in Review*, August 2006. Found at http://pedsinreview.aappublications.org.

[21] The federal "340B" program, named after Section 340B of the Public Health Service Act portion of the Veteran's Health Care Act (1992), requires pharmaceutical manufacturers to provide discounted prices to certain "covered entities" (such as HTCs).

[22] *Parent Empowerment Newsletter (PEN)* issues, which serves the hemophilia community. See, for example, “Hemophilia, Incorporated: How the Hemophilia Business Works in America, and What Threatens to Change It.” November 2004, LA Kelley Communications, Inc., Georgetown, MA.

[23] For a variety of legal and other reasons, insurers are unlikely to state this possibility in their submissions and comments about the bill. However, policymakers and other stakeholders should be aware of this possible outcome.

[24] *Health Insurance Mandates in the States*, 2007 and 2008. Council for Affordable Health Insurance, found at www.cahi.org.

[25] http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+38.2-3418.3. Virginia Code Section 38.2-3418.3.

[26] It should be noted that respondents submitted conflicting statements about whether Medical Assistance programs would be subject to the mandated requirements of HB 1105. See also Section I.