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FISCAL IMPACT STATEMENT

LS 6402
BILL NUMBER: SB 157

NOTE PREPARED: Feb 22, 2008
BILL AMENDED: Feb 21, 2008

SUBJECT: Health Programs.

FIRST AUTHOR: Sen. Miller
FIRST SPONSOR: Rep. C. Brown

BILL STATUS: CR Adopted - 2nd House

FUNDS AFFECTED: X **GENERAL**
X **DEDICATED**
FEDERAL

IMPACT: State & Local

Summary of Legislation: (Amended) This bill does the following.

Opioid Treatment Programs: This bill changes the term "methadone treatment" to "opioid treatment" for purposes of the law concerning certification of opiate addiction treatment facilities. It requires the Division of Mental Health and Addiction to adopt rules on: (1) standards for operation of an opioid treatment program; (2) a requirement that the opioid treatment facilities submit a current diversion control plan; (3) fees to be paid by an opioid treatment facility; and (4) a required statement that provides that the patient will be driven by another person from the facility.

The bill also requires an opioid treatment program to: (1) periodically and randomly test a patient for the use of specified drugs and to include the drug testing procedure in the opioid treatment program's diversion control plan; and (2) terminate the patient's treatment at the facility within14 days if the drug test is positive for an illegal drug other than the drug being used for the patient's treatment. It specifies violations and penalties. The bill repeals the expiration of current law requiring a methadone diversion control and oversight program.

Umbilical Cord Blood Bank: This bill requires the office of the Secretary of Family and Social Services Administration (FSSA) to form a nonprofit corporation to establish and operate an umbilical cord blood bank. It also requires suitable postnatal donations to be available for medical treatments and scientific research. The bill requires the nonprofit corporation to develop a process for physicians, nurse midwives, and participating hospitals to inform pregnant patients of the option to make postnatal donations following delivery of a newborn infant. The bill also requires the nonprofit corporation to establish an umbilical cord blood donation initiative to promote public awareness concerning the medical benefits of umbilical cord

blood.

(The introduced version of this bill was prepared by the Health Finance Commission.)

Effective Date: July 1, 2008.

Explanation of State Expenditures: *Department of Mental Health and Addiction (DMHA)*: The bill requires DMHA to establish a central registry to maintain information concerning each patient served by an opioid treatment program. The Indiana Central Opioid Patient Electronic (ICOPE) registry is currently online and in the implementation stage and assigns a unique identifier to each patient treated in the state by opioid treatment programs (OTPs). The information contained in this registry will be provided by the OTPs at least every month. The annual cost for the registry in the FY 2008 budget included $100,000 for the ICOPE program. This amount is the annual cost for operation and maintenance of the central registry required in the legislation.

The bill also requires DMHA to prepare and submit a biennial report to the Legislative Council and the Governor concerning the treatment offered by opioid treatment programs. This report is currently produced by DMHA and contains all information required in the legislation. The requirement that the report be prepared and submitted would have no additional fiscal impact on DMHA.

(Revised) *Umbilical Cord Bank*: The cost of the public umbilical cord blood bank will depend on the General Assembly to appropriate funds, the amount of private donations available to subsidize the public cord blood bank, the amount of revenue to be realized from sales, and subsequent administrative actions taken by FSSA to form the nonprofit corporation and any subsequent actions by the board of directors to administer the program. Approximately $1.06 M is estimated to be required for direct collection, testing, and banking costs necessary for the public umbilical cord blood bank to reach the minimum size required to apply for federal grant funds. This estimate does not include administrative, marketing, or training costs required by the bill that would depend on administrative actions. The availability of federal grant funds is on a competitive basis.

(Revised) *Background and Additional Details-*

Opioid Treatment Programs: Indiana currently provides public funds to not-for-profit OTPs only. Indiana directly funds two not-for-profit OTPs from federal Substance Abuse Prevention and Treatment (SAPT) block grant funds to subsidize certain patients, based on income limitations. This reduces out-of-pocket expenses to these patients and allows clinics to charge lower-income patients on a sliding scale. Currently, there are two not-for-profit OTPs in the state, with a third scheduled for opening in Porter County.

Umbilical Cord Bank: As a point of reference, the National Marrow Donor Program has estimated that 5 to 7 years and approximately $10 M to $16 M is necessary to develop and annually store sufficient units in a cord blood bank for the bank to reach a break-even point on an annual cash flow basis. Additionally, the Texas Cord Blood Bank established in 2004 has received state appropriations of $6.2 M and was awarded $1.66 M in federal funds in the 2007 round of competitive federal grants.

The bill requires FSSA to form a nonprofit corporation to provide for the operation of a public umbilical cord blood bank. The board of directors is to consist of ten members: the Commissioner of Health, the Secretary of FSSA, the Secretary of Commerce, the Director of the Office of Minority Health and six individuals with specific professional credentials to be appointed by the Governor. The board is required to appoint an

advisory board to be responsible for reviewing applications for the purchase of postnatal donations determined to be ineligible for transplant use. The bill also authorizes the board to contract for the management and administrative operations of the public umbilical cord blood bank and requires the acquisition of adequate liability insurance. The bill would also allow the board without the approval of the Attorney General and subject to the approval of the State Budget Agency to employ legal counsel, technical experts, and other officers, agents, or employees necessary to operate an umbilical cord blood bank. The cost of this provision would depend on appropriations, other financial resources that would be available, and administrative actions of the board.

The bill requires the nonprofit corporation to educate health care professionals about the procedures necessary to collect and maintain postnatal donations following the birth of an infant. The corporation is required to develop procedures concerning patient informed consent and privacy. The corporation is required to establish a public awareness initiative to promote (1) the importance of donating to a public cord blood bank and (2) the opportunity to make postnatal donations on the birth of an infant. The public awareness campaign must include the distribution of written materials containing specified information to specified persons and licensed facilities.

The bill requires the nonprofit corporation to develop a process for physicians, nurse midwives, and participating hospitals or birthing centers to inform eligible candidates of the opportunity to make postnatal donations to the public umbilical cord blood bank. The bill specifies that a patient may not be charged for the collection, storage, or donation to the public umbilical cord blood bank.

Startup Funding Estimate: The U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), requires that public cord blood banks have 600 transplantable cord blood units and a viable minority outreach program developed before an application will be accepted for competitive grants currently available to expand the national cord blood inventory. In order to reach the level necessary to apply for federal funding (600 units) it is estimated that only 30% of the total collected units will ultimately be placed in the bank due to stringent quality standards that must be met. This would require the initial collection of at least 2,000 cord blood units. Testing costs are significant, with the direct cost of testing reported to be between $1,000 and $1,700 for each unit banked. Testing costs for collected units that are discarded prior to storage are estimated to be approximately $500 per unit. Annual storage costs for banked units are estimated to average $50 per unit. Total testing cost required to reach the number of banked units necessary to apply for federal funding is estimated to range from $1,315,000 to $1,735,000.

Collection costs are assumed to be donated by the participating hospitals. If collection costs cannot be absorbed by the hospitals, this could result in additional expense to the public cord blood bank. Collection of the cord blood units includes the completion an extensive medical history by the mother as well as the collection of the cord blood. As a point of reference, Medicaid currently has a $55 charge for medically necessary aspiration of cord blood. If only collection costs for the aspiration of cord blood at the Medicaid reimbursement would be paid by the public cord blood bank, an additional $110,000 would be necessary for the collection of the first 2,000 units.

Existing cord blood banks are reported to experience a transplant utilization rate of less than 1% with the charge for a transplantable unit being approximately $15,000. If this experience is assumed to apply to the first 600 banked cord blood units, 6 matches might be expected. $90,000 may be realized in revenue from this source.

The bill also allows the cord blood bank to make units not eligible for banking available for research

purposes. Umbilical cord blood units or placentas used for research purposes may be sold for $185 to $505 depending on the level of processing performed. This source of revenue is estimated to generate revenue in the range of $259,000 to $707,000.

It is assumed that the collection program will be subject to a phased implementation with the initial program being implemented in the Indianapolis metropolitan area to include Marion and the surrounding counties. This geographic area had 25,600 live births in 2005, about 30% of the total annual births in the state. If only 10% agree to donate their child's cord blood (2,600), the program would have more than the volume estimated to be necessary to bank the initial 600 units required to apply for federal funding. (The associated costs would also be higher as well.)

The bill requires the nonprofit corporation to establish an umbilical cord blood donation initiative to promote public awareness of the purposes of cord blood banking and the opportunity to donate to a public cord blood bank. This information is required to be distributed in a written format. The program is also required to educate health care professionals about collection procedures and requirements as well as other administrative requirements to implement the cord blood bank. The cost of these provisions will depend on the number of initial participating hospitals and physicians.

Other State Initiatives: The New York Blood Center, one of the largest public cord blood banks with about 35,000 cord blood units, reports that processing a unit of cord blood costs between $1,000 and $2,000 depending on how it is collected and stored and the location of the bank. This bank reported that their operations "about break-even" since they have such a large inventory of units. Most of the nearly two dozen public banks in the country rely on private donations to operate.

Federal initiatives are making limited funding available with the intent of increasing the national inventory of cord blood units available. HRSA awarded $12 M in grants in 2006 to the first group of cord blood banks to begin collections for the National Cord Blood Inventory. A second round of competitive grants was distributed to the original six grantees plus two additional cord blood banks in September 2007. HRSA requires that public cord blood banks have 600 transplantable cord blood units and have a viable minority outreach program developed before an application will be accepted for the competitive grants.

Several states have funded the startup and operations of state-sponsored cord blood banks. New York announced construction of a new $10 M umbilical cord blood bank to be operated by the State Health Department's Wadsworth Laboratory with about 20 employees.

Texas started the Texas Cord Blood Bank in 2004 with a $1 M startup grant, promising up to $3.5 M in matching funds for the facility. The first unit of cord blood was collected in June 2005; in November of the same year, the facility was awarded another $1.2 M in state matching funds after reaching 1,000 collected units. The facility has also been raising funds in the community. In May 2007, the Texas legislature appropriated another $4 M to assist in the collection of cord blood units. Additionally, the Texas Cord Blood Bank was awarded $1.66 M in federal funds in the 2007 round of HRSA competitive grants. As of November 2007, the Texas Cord Blood Bank reported six participating hospitals in the state. Texas officials reported that the program needed to collect about 6,000 units to be financially self-sustaining.

New Jersey appropriated $2.5 M annually in April 1998. However, in 2006 the appropriation and the authorizing language was discontinued.

Explanation of State Revenues: *DMHA*: Proposed increases of the out-of-state patient fees along with the

creation of in-state fees are required by the bill to be sufficient to cover the cost of implementation. Expenses experienced by DMHA in FY 2006 for their oversight of OTPs totaled $313,000. The legislation requires that user fees for OTPs cover the cost of providing oversight and regulation of the clinics. These fees are not to exceed $75 per user. Currently, only out-of-state users are charged a $20 user fee. The estimated population of OTP users in 2007 is 11,288, of which 5,539 are expected to be out-of-state patients. Revenue to DMHA from the $20 user fee for the out-of-state population until May 14, 2009, is expected to be $111,000. The OTP user population in 2008 is estimated to be 12,050. Assuming the maximum user fee, revenue to DMHA on May 15, 2009, is expected to be $904,000, an increase of $793,000 from the prior year. Actual revenue will depend on the costs incurred by DMHA for regulation of OTPs as fees charged cannot exceed costs.

(Revised) The legislation adds that individuals that receive treatment from OTPs must sign a statement that they will be driven away from the facility by a responsible person after receiving opioid treatment medications. The impact on user fees from any change in OTP use resulting from this provision is unknown.

(Revised) Additionally, the legislation adds that OTPs must periodically randomly test patients for select drugs during an individual's treatment program. If a patient tests positive for substances defined in the legislation, the OTP is required to terminate the patient's treatment at the OTP facility. User fees paid to DMHA from OTPs are collected for all patients that are entered into OTP patient records. If these patients are removed from the program, but have been included in the OTP records, OTPs are still responsible for the annual user fees for these individuals.

OTPs are required to pay DMHA user fees for all patients treated during the last calendar year on May 15th of the subsequent year. This means that fees DMHA receives on May 15, 2008, will be for calendar year 2007. The legislation has an effective date of July 1, 2008, which is after the date that fees are paid to the Division. DMHA will experience their first increase in revenue from user fees in the legislation in 2009.

If an OTP either (1) violates any of the laws dealing with methadone diversion, control, and oversight, (2) permits, aids, or abets the commission of an illegal act in an OTP facility, or (3) conducts a practice found detrimental to the welfare of an OTP patient, the Director of DMHA is authorized to take any of the following actions: *(a)* issue a letter of correction, *(b)* reinspect an OTP, *(c)* deny renewal or revoke either approval to operate as an OTP or the certification of the OTP, and *(d)* impose a civil penalty not to exceed $10,000. Any revenue from civil fees is likely to be small.

Court Fee Revenue: If additional civil or court actions occur and court fees are collected, revenue to the state General Fund may increase. A civil costs fee or a court costs fee of $100 would be assessed when a case is filed, 70% of which would be deposited in the state General Fund if the case is filed in a court of record or 55% if the case is filed in a city or town court. In addition, some or all of the document storage fee ($2), automated record keeping fee ($7), judicial salaries fee ($17), public defense administration fee ($3), court administration fee ($3), and the judicial insurance adjustment fee ($1) are deposited into the state General Fund.

<u>*Background Information*</u>: Currently, the state collects revenue from for-profit opioid treatment facilities in the state. There are 14 opioid clinics in the state, of which 3 are considered not-for-profit clinics, one clinic operates under federal guidelines (and therefore is not under DMHA oversight), and 11 of the 14 are considered for-profit opioid clinics. Clinics can charge sliding scale fees for lower-income individuals, and there is financial assistance available for indigent individuals that is provided from the federal SAPT block

grant. Indiana Medicaid can also provide limited coverage for OTP services. The revenue collected from these treatment programs currently comes in the form of out-of-state patient fees. Currently, there are no fees charged to Indiana residents that utilize the treatment programs, and there are no program certification fees collected. All revenue collected from OTPs currently comes from the out-of-state user fees assessed at $20 per person, which generated a total of $102,100 in FY 2006 for 5,105 out-of-state patients. Currently, in-state users are not assessed a fee. All revenue collected from OTPs is deposited into the Opioid Treatment Diversion and Oversight Program fund which is administered by DMHA.

DMHA reports that the out-of-state fees received by the state are not paid by the patients, but are actually financed by the OTP. Increasing the fees for out-of-state residents might shift the cost to the patients in some form, or the fees may continue to be financed by OTPs in the state. The increase of the out-of-state user fees may increase the amount charged to patients for treatment, potentially decreasing the demand for OTP service. This potential decrease in demand for treatment can affect the revenue collected by DMHA for out-of-state patient fees. The actual decrease in out-of-state demand for treatment associated with increasing costs is indeterminable.

Explanation of Local Expenditures: (Revised) *Umbilical Cord Bank*: Participating county-owned hospitals would be required to offer each eligible maternity patient the option of making a postnatal donation following delivery at the facility. Participation by hospitals and birthing centers is optional.

Explanation of Local Revenues: *Court Fee Revenue:* If additional civil or court actions occur, local governments would receive revenue from the following sources. The county general fund would receive 27% of the $100 civil or court costs fee that is assessed in a court of record. Cities and towns maintaining a law enforcement agency that prosecutes at least 50% of its ordinance violations in a court of record may receive 3% of court fees. If the case is filed in a city or town court, 20% of the court fee would be deposited in the county general fund and 25% would be deposited in the city or town general fund. Additional fees may be collected at the discretion of the judge and depending upon the particular type of case. However, additional fee revenue is anticipated to be small.

State Agencies Affected: DMHA, OMPP, FSSA.

Local Agencies Affected: Trial courts, city and town courts.

Information Sources: Cathy Boggs, DMHA; Jessaca Turner-Stults, FSSA; Terry Whitson, Indiana State Department of Health; Scott Zarazee, Indiana State Department of Health; *Report to the Health Finance Commission and General Assembly* prepared by DMHA; *Indiana Opioid Addiction Treatment Program Report, 2005*, prepared by FSSA and DMHA; *Report to the General Assembly, Public Act 06-77, An Act Concerning the Establishment of a Public Umbilical Cord Blood Bank*, January 5, 2007, J. Robert Gavin, MD, MPH, Commissioner, Department of Public Health, State of Connecticut at Cord Blood, Establishing a National Hematopoietic Stem Cell Bank Program, Committee on Establishing a National Cord Blood Stem Cell Bank, http://www.ct.gov/dph/lib/dph/governmental_relations/2007reports/public_umbilical_cord_blood_bank_report.pdf. Program, Institute of Medicine of the National Academies, at: http://www.nap.edu/openbook.php?record_id=11269&page=221..

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