Approved: February 22, 2006
Date

MINUTES OF THE SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

The meeting was called to order by Chairman James Barnett at 1:35 P.M. on February 8, 2006 in Room 231-N of the Capitol.

All members were present.

Committee staff present:
Emalene Correll, Kansas Legislative Research Department
Terri Weber, Kansas Legislative Research Department
Norm Furse, Office of Revisor of Statutes
Diana Lee, Office of Revisor of Statutes
Morgan Dreyer, Committee Secretary

Conferees appearing before the committee:
Dr. Michael Bond, Public Finance Economist

Others attending:
See attached list.

Vice Chairwoman V. Schmidt offered information on the Minimum age requirements for joining the NMDP Registry.

Presentation on Kansas Specific Proposal for Medicaid Reform

Upon calling the meeting to order Chairman Barnett introduced, Dr. Michael Bond, Public Finance Economist who began by stating a brief overview of his Biography, and that he would be giving a detailed presentation on a Kansas specific proposal for Medicaid reform. Highlights of his presentation include:

Biography of Michael Bond, Ph.D., Senior Fellow in Health Care Policy

Flint hills center studies addressing Medicaid fiscal issues.

Reforming Medicaid In Kansas: A Market-Based Approach

What's wrong with Medicaid
1. Reform Step 1: Create an insurance and provider exchange
2. Reform Step 2: All plans will be prepaid
3. Reform Step 3: The Medicaid health credit will be actuarially risk-adjusted
4. Reform Step 4: Medicaid will reinsure smaller plan
5. Reform Step 5: All beneficiaries will receive "reverse" health saving accounts
6. Reform Step 6: The disabled and elderly will enroll in prepaid plans
7. Reform Step 7: Allow Medicaid beneficiaries to buy into private plans
8. Reform Step 8: All market-distorting practices and policies are discontinued
9. What happens in real markets for health care
10. Summary and conclusion
11. About the author, Michael Bond, Ph.D.

A copy of his testimony is (Attachment 1) attached hereto and incorporated into the Minutes as referenced.

The Chair asked for questions or comments from the Committee. Questions came from Senator Brungardt reform on Medicaid in Kansas.

Action on SB 426
SB 426–An act relating minors; concerning the donation of blood

Chairman Barnett then asked the Committee if there was no objection that he would like to ask the Committee to reconsider its action on SB 426. The Chair has made presented the Committee with a

MINUTES OF THE Senate Public Health and Welfare Committee at 1:35 P.M. on February 8, 2006 in Room 231-N of the Capitol.

document called "White Paper," about bone marrow, and actual age of donations. A copy of his document is (Attachment 2) attached hereto and incorporated into the Minutes as referenced. The Chair raised the question if it would be better at this point in time to return to the base bill.

Senator Wagle made a motion to reconsider the action on SB 426 and return to the bill. It was seconded by Senator V. Schmidt.

Senator Journey stated that he thought the appropriate procedure is to grant the motion to reconsider and then go back and refer to the appropriate language, and another motion to move it out after it has been agreed to amend it.

The Chair responded that he had contacted Norm Furse about how to go about this situation , and if it is done by consensus then the Committee can have an actual vote.

The Chair asked to have a vote on reconsideration of the bill, and the motion carried.

Chairman Barnett then confirmed with Norm Furse the proper procedure on how to advance the bill without the amendment..

Senator Journey made the motion to withdraw the amendment. It was seconded by Senator V. Schmidt and the motion passed.

The Chair stated that they needed to advance the bill.

Senator V. Schmidt made the motion to move SB 426 in its original form out favorably. It was seconded by Senator Palmer and the motion passed.

Action on HB 2284
HB 2284–Right to breastfeed; jury duty exception

Chairman Barnett asked the Committee what they wanted to do with this bill.

Senator V. Schmidt made a motion to move **HB 2284** out favorably. It was seconded by Senator Brungardt.

The Chair stated that the Committee would take the bill back out as it was returned to them, to the full Senate to have their opportunity again to vote or amend the bill.

The motion passed.

Adjournment

As there was no further business, the meeting was adjourned at 2:22 p.m.

The next meeting is scheduled for Thursday, February 9 , 2006.

No Attendance Sheet
was returned to Committee Secretary for
Senate Public Health and Welfare Committee

Feb. 8, 2006

Michael Bond, Ph.D.
Senior Fellow in Health Care Policy

Michael Bond, Ph.D., is an adjunct scholar for the Kansas-based Flint Hills Center for Public Policy, the Senior Fellow in Health Care Policy at The Buckeye Institute, a Professor of Finance at Cleveland State University and an adjunct lecturer at the Weatherhead School of Management at Case Western Reserve University. He has taught health care finance along with numerous other courses. He is an active consultant and has worked with over 150 law firms and companies on numerous issues. His work on Medical Savings Accounts (MSAs) and health-care policy reform has received national attention and appeared in a wide range of professional and popular publications, including *Health Care Financial Management*, *Public Personnel Management*, *Compensation and Benefits Review*, *Benefits Quarterly*, and *Business Horizons*. Along with over 70 articles and presentations, he is the author of the nation's first practical guide to establishing MSAs (published by The Buckeye Institute in 1997). He also co-authored a guide to reforming Medicaid using a market based plan (published by the Buckeye Institute in 2003). This resulted in the establishment of a Medicaid Commission in Ohio that adopted many of the proposals in their final report. The State of Florida recently proposed Medicaid reforms based on his "Insurance & Provider Exchange Model." Bond earned his Ph.D., M.A. and B.A. in economics from Case Western Reserve University and serves as an advisor on Medicaid to South Carolina Governor Mark Sanford.

Senate Public Health & Welfare Committee
Date: Feb 8, 2006
Attachment #1

FLINT HILLS CENTER
FOR PUBLIC POLICY

POLICY PAPER

Volume 3, Issue 3

February 2, 2006

REFORMING MEDICAID IN KANSAS: A MARKET-BASED APPROACH

BY DR. MICHAEL BOND

Medicaid faces serious challenges in Kansas and across the U.S. The joint Federal/State program suffers from unsustainable budget growth that threatens the fiscal solvency of both the states and the Federal Government.[1] In addition, the level of satisfaction among Medicaid's beneficiaries is troublingly low.[2] A plan that is unable to deliver a satisfactory level of service and is actively driving the nation into bankruptcy is a plan that needs to be reformed.

Policymakers in Kansas should take the following steps to improve the Medicaid program:

- Create a health mart (an Insurance and Provider Exchange) where providers offer prepaid services to beneficiaries.
- Establish actuarially adjusted credits for beneficiaries to purchase care they need from competing providers.
- Offer "reverse health savings accounts" for beneficiaries to pay them for engaging in behavior that leads to better health outcomes.
- Eliminate counter-productive and anti-market schemes such as Certificate of Need Laws and formularies.

Undertaking reform of such a complicated issue is, of course, a major effort on the part of Kansas. State policymakers can be comforted that such reforms are being implemented right now elsewhere.[3]

I. WHAT'S WRONG WITH MEDICAID?

As mentioned in an earlier publication by The Flint Hills Center, the fundamental problem facing Medicaid is the lack of a real marketplace.[4] In a traditional market, buyers acting in their own interest purchase goods and services with transparent prices. Sellers/providers seek to maximize their profit/incomes by offering goods and services that consumers want to buy. They also add to their bottom line by delivering those goods and services more efficiently over time and by improving the quality of their existing product. This market approach, while by no means perfect, works better than the command-control approach that has evolved.

Medicaid (and much of health care) lacks such a marketplace. There is little or no transparency in the cost of medical services. Consumers do not pay any significant portion of the cost of their care and therefore have little incentive to economize. Since they bear little or none of the cost of care they are less likely to lead healthy lifestyles that can significantly reduce medical needs.

Bureaucratic decree, rather than natural supply and demand, determines prices. Providers often have no incentive to control unnecessary utilization and/or treat health problems in a cost-effective manner. In fact, tort litigation and other pressures create an

incentive for providers to allow and/or encourage over utilization. There is little incentive to innovate in the delivery of health care. Finally, since beneficiaries are not really consumers in the traditional sense they lack the empowerment to receive quality care.

Looking to additional price controls and government regulations in Medicaid will simply make the problem worse. To fix the problem, policymakers must create a real marketplace. This requires making enrollees the buyer of the medical services they need and allowing competing providers to sell them those services. Beneficiaries need to have incentives to follow a regimen of health behavior and providers need profit/income incentives to continually innovate in the delivery of services.

II. REFORM STEP 1: CREATE AN INSURANCE AND PROVIDER EXCHANGE

Kansas Medicaid (KM) should establish an Insurance & Provider Exchange (IPE). The IPE is nothing more than a state-run mart where Medicaid beneficiaries will purchase their health care.

Providers will offer packages of services to the enrollees at the IPE. The role of the state will change from being the buyer of the health care to facilitating a real marketplace in Medicaid. KM will provide beneficiaries with funds to buy their own health care. They will mandate minimum required benefits and services from providers.

KM will require complete transparency on the part of providers with regard to the services that they offer to enrollees. KM will assist beneficiaries in selecting health products that best meet their needs but the actual choice will be made by the enrollees. KM will give beneficiaries a Medicaid Health Credit (MHC) to buy the coverage they want at the IPE from competing providers.

III. REFORM STEP 2: ALL PLANS WILL BE PREPAID

One of the major problems facing Medicaid is the large scale use of fee-for-service (FFS) delivery systems. Essentially, the beneficiaries find a doctor or emergency room or are admitted to a hospital for services. KM then pays the provider a fee.

This system has three major flaws. First, efforts to limit usage with arbitrary bureaucratic edicts yield highly unsatisfactory results. Health care is very complicated and no bureaucracy can effectively design a rationing system to control usage in a manner that contains costs while preventing negative health outcomes. On the demand side, the beneficiary pays little or nothing out of pocket and therefore has little incentive to economize on using unneeded care. On the supply side, providers are left with an incentive to deliver services that are not appropriate given that payments follow services rather than outcomes.

Second, these payments paid to providers are not only far removed from outcomes, but they are also equally far removed from true prices based on the interaction of supply and demand. Instead, "prices" are set bureaucratically through government schemes. They are, in effect, price controls. If the rates are set too high there will be too much health care delivered (a surplus). If they are set too low there will be too little care provided (a shortage). In services like health care where quality is important these shortages can take the form of lower actual quality (5 minute office visits), long waiting periods and actual inability to get services at all. Further, rates set below market cause fewer providers to deliver services and promote the competition needed to lead to innovative medical practices.

Finally, FFS often produces episodic health care where problems are (maybe) treated instead of being prevented. Prepaid plans benefit financially from patients having better health and have an incentive to provide preventative care that reduces major health problems in the future. Further, they have an incentive to cost effectively manage existing conditions because their profits/incomes will be higher. It makes much more sense to get a pregnant beneficiary proper prenatal care then it does to spend a fortune on treating a low birth-weight baby. Since the plans can generate a higher income/profit by reducing costs, they have a strong incentive to

innovate. Competition between the plans then forces prices down to their marginal cost. The result will be a slowdown in the rate of medical inflation that Medicaid faces. This innovation will put the plan(s) on a more sustainable fiscal basis.

IV. REFORM STEP 3: THE MEDICAID HEALTH CREDIT WILL BE ACTUARIALLY RISK-ADJUSTED

Insurance companies are in the business of managing risk. Better drivers pay lower insurance premiums. Teenagers as a group are not better drivers and pay higher premiums. Younger people live longer and pay lower life insurance costs. Women live longer than men and pay lower life insurance rates. And in a properly-designed health insurance market sicker beneficiaries would pay more than healthier beneficiaries.

Due to quirks in history there effectively has not been a real market for health insurance. First, many traditional carriers practiced community rating where equalized rates encouraged sicker people to enroll and healthier people to drop out of the insurance pool. Second, tax laws encouraged the purchase of health care through employers. Employer-based insurance is, therefore, just a reallocation of employee compensation to health insurance instead of wages to minimize income taxes.

The above proposed Medicaid reform involves beneficiaries buying prepaid plans from competing providers. Existing Medicaid "managed care" plans are generally set up through selective contracting. Theoretically there may be choices for beneficiaries, but as a practical matter they tend to wind up in one plan over time.

The payment to the plan from Medicaid is an administered price (price control) and is not risk adjusted for each enrollee. While the enrollment in the plans is guaranteed, the failure to risk-adjust payments encourages "cherry picking" by prepaid plans. With the advent of easy to use software it is a relatively simple task to risk-adjust the MHC. While risk adjustment is not perfect, it significantly reduces the incentive to enroll only healthy beneficiaries.[5]

In addition to risk-adjusted Medical Health Credits (MHCs) there should also be a requirement of an actuarial payment from one provider to another if a chronically-ill enrollee switches plans. First, this will further minimize a plans desire to avoid signing up ill beneficiaries. Second, it will encourage the provider that the beneficiary is currently enrolled with to offer quality care focused on disease management. The combination of risk adjustment and a transfer actuarial payment will give plans a strong incentive to compete vigorously for all beneficiary business.

V. REFORM STEP 4: MEDICAID WILL REINSURE SMALLER PLANS

A central tenet in reforming Medicaid is creating a competitive marketplace where beneficiaries can obtain their health care. Monopolies and oligopolies are bad for consumers in any industry – health care is certainly no exception.

In order to make reform work in Kansas it is imperative that choices exist for enrollees. It is also necessary for these providers to be prepaid to control utilization and give incentives for cost reducing, quality promoting innovations. But the benefits of prepaid plans also raise a potential problem in terms of smaller providers who may wish to enter the marketplace.

For a provider to have a reasonable idea of what health costs will be in a current year requires a significantly large pool of coverages (say 5,000 lives). Larger prepaid plans will have an incentive to offer coverage to Medicaid beneficiaries if the enrollees' buying power is risk-adjusted and there is flexibility on the benefits package.

While many of these organizations are indeed effective and innovative, history shows that start-up entrepreneurs often develop revolutionary new methods and products. The problem is that a prepaid practice of, say, ten innovative doctors that enroll 1,000 beneficiaries could be wiped out if they are unlucky enough to sign up a few very high-cost patients. Thus, good ideas that could reduce Medicaid costs and improve its quality may never

make it to the marketplace. This problem, of course, is particularly acute in rural areas like Kansas.

The solution to this problem involves KM "reinsuring" smaller practices if they run into high costs. Actuarially, the risk to a prepaid plan becomes greater given a smaller number of enrollees. KM could use a sliding scale framework with very small plans having a much smaller effective stop-loss limit than medium-size providers. Large prepaid groups would not receive reinsurance. To maintain the incentive for providers to control unneeded utilization there would need to be some financial risk once the reinsurance begins. As with the reinsurance itself, this should be set up on a sliding scale with smaller groups being required to cover a smaller proportion of expenses in the reinsurance range.

As with the private sector, providers need to have flexibility in designing their product. The current Medicaid system has a federally required benefits package with states having the ability to expand the minimum required services providers must cover. Generally, states have operated with a "one-size-fits-all" mentality on the mandated benefits package. This makes no sense given the diverse population that Medicaid covers. Providers must be able to market to specific groups as in the private sector. This specialization and division of labor will increase efficiency and lower medical inflation.

Just as important, it will improve the quality of care for beneficiaries. Since payments for beneficiaries will be risk-adjusted, plans will have an incentive to enroll both healthier and sicker beneficiaries. Practices specializing in the treatment of those afflicted with AIDS could develop alongside those who provide OB/GYN services. As in the private sector, plans may implement an overall benefit limitation.

VI. REFORM STEP 5: ALL BENEFICIARIES WILL RECEIVE "REVERSE" HEALTH SAVINGS ACCOUNTS

Incentives matter. The failure to recognize this is one of the major problems of Medicaid and, indeed, all of health care. The proposed reform plan will get the incentives right and produce cost-effective, higher-quality care for the poor.

Some have suggested that a better alternative to the supply-side control of prepaid plans is demand-side control of health care usage through significant cost-sharing. Indeed, the widely heralded Rand Health Insurance study showed significantly less usage of health care when those enrolled had higher levels of cost-sharing. Anyone familiar with the basic laws of economics could predict the result. The law of demand had its impact.

Health Savings Accounts (HSAs) are another tool touted as a solution to the problem of using health care demand and inflation. How do they work?

Suppose families have a health plan with 100 percent coverage with an average premium cost of $10,000 per year. Under an HSA plan they or their employer increase the deductible on the plan from zero (in this example) to say, $4,000. Since the firm or insurance carrier has less cost risk the premium on the plan will drop. How much is an actuarial issue. Health expenditures tend to be highly skewed in any given year. One rule of thumb is the 80/20 assumption where 20 percent of individuals incur 80 percent of all costs in a year. In other words, a small number of sick people run up most of the expenses annually.

The effect of these skewed expenditures on increasing the deductible to $4,000 is that "premium" would not decline by an equal amount. The actual reduction depends on several factors but assume it is $2,800 so that the new premium is $7,200. Proponents argue that the high deductible will cause enrollees to use health care more carefully, and even most critics agree this will happen below the deductible.

Given the $4,000 deductible the plan allows for a deposit of $2,800 to each HSA. Families with expenditures of less than $2,800 have unused funds and obviously benefit from the HSA. Those with expenses above $2,800 now have to pay out-of-pocket up to the deductible of $4,000. They are financially worse off.

Proponents argue this is not a major issue in the private sector for two reasons. First, the out of pocket risk is not particularly large in most cases. Second, it is not the same individuals who are sick every year. The National Bureau of Economic Research examined a large set of medical expenditures and found, as expected, that 10 percent of those covered generated 80 percent of spending in a year. But over a 35-year work life, 55 percent of employees ran up 80 percent of the medical expenses. In other words, there is declining persistency in spending over time. This has the effect of leaving the vast majority of those using HSAs with unused balances if they are enrolled in the plans over a long period of time.[6]

But these can be significant issues in Medicaid. First, from above, there is likely to be an increase in out-of-pocket risk to beneficiaries. This is obviously a much greater burden for the poor than for wealthier enrollees. Further, the Rand Study showed some unfavorable health outcomes for low-income groups when they were subjected to cost-sharing. Second, people move on and off of Medicaid over time. This does not allow for the declining persistency that occurs in the private sector and makes it less likely that a high percentage of beneficiaries will have unused HSA balances. As such, a private sector type HSA may not be advisable.[7]

A better way to generate the incentives that HSAs can produce is by "reversing" the accounts. KM should give every Medicaid beneficiary a reverse HSA (RHSA). The accounts will have a zero balance initially. KM would then add dollars to the account when beneficiaries use health care in an effective and responsible manner.

Medicaid in many states, for example, suffers from a significant problem of enrollees using hospital ER's for non-life threatening illnesses. KM could pay beneficiaries a portion of the savings from getting coverages to use a physician for their primary care. Large savings could result by paying pregnant women to obtain proper prenatal care and avoiding low birth-weight babies. The same is true of obtaining a full panel of immunizations for children and for diabetes spots and blood pressure checks for adults.

Funds in the account could be used to purchase additional medical care or rolled over for future purchases. They could also be used to pay for medical care when the beneficiary leaves Medicaid. The RHSA would be a money saver for KM with credits to account being a fraction of the expected actuarial savings from discouraging "bad" behavior and encouraging "good" behavior.

This type of HSA does not expose beneficiaries to out-of-pocket costs and is not dependent on a long enrollment period for effectiveness. In addition, since funds may be rolled over and taken out of the accounts at a later time they will produce a "reverse" working capital effect for Medicaid. The State of Florida's reform plan has this account as part of its design.

VII: REFORM STEP 6: THE DISABLED AND ELDERLY WILL ENROLL IN PREPAID PLANS

As with the acute care population, Medicaid beneficiaries who are disabled and/or elderly will enroll in prepaid plans. They, too, will receive risk adjusted MHCs. The purpose of the prepaid plan, as above, is to limit unnecessary usage and create incentives for innovations in the delivery of care. This population is a minority in state Medicaid plans but accounts for majority of expenditures. As such, it is crucial that providers to these populations deliver quality care in a cost-effective manner. In addition, this group of enrollees will also receive RHSAs to encourage appropriate medical behavior that results in cost savings.

A central tenet of the proposed reform in this area involves changing the bottom line of providers. Many institutions that deliver services to Medicaid receive payment using a cost-based methodology. This, of course, is just another administered pricing scheme. And, like other price control schemes, it encourages inefficiency and low quality. The development of the MHC will make beneficiaries a sought-after "customer" and competition between providers will lower medical inflation.

Nursing homes and other institutions that provide services to Medicaid should become prepaid in nature. There are two ways this can happen. One is for the provider to list their services at the IPE. The other is for managed care companies to negotiate with these institutions the same way they negotiate with physicians and hospitals. The marketplace will determine which mechanism is most effective. Prepaid plans would have an incentive to develop innovative methods to deliver needed care in a cost-effective manner.

The RHSA can encourage behavior that lowers costs. For example, the mentally disabled sometimes stop taking medications that allow them to function in a reasonably normal manner and avoid very expensive institutionalizations. Documented care visits and usage of effective prescriptions could be rewarded by deposits to the RHSA. As well, offering RHSA funds to loved ones could allow parents and other family members to care for the mentally and physically disabled in a non-institutional setting.

Here the RHSA would essentially function as a "cash and counseling" program. These limited experiments around the country have proven very popular with the disabled. Beneficiaries who are eligible for Medicaid coverage of nursing home care could instead receive RHSA funds if they are able to obtain services in a less-costly environment. This would allow some to stay at home as opposed to assisted living facilities. Here, too, the ability of family members to receive payment from the RHSA could significantly reduce Medicaid's nursing home costs.

It is, of course, possible that allowing payments to family members could create an "out of the woodwork" effect. That is, individuals currently not enrolled in Medicaid may sign up for the plan to access these dollars. It is crucial that estate recovery efforts be highly effective to minimize this occurrence. There are estimates that as many as 90 percent of those enrolled in Medicaid coverage for nursing homes have done some type of asset planning to qualify for their coverage. Further look-back periods and recovery programs for those seeking Medicaid nursing home coverage would produce larger potential losses in estates to family members and reduce the incentive to game the RHSA.[8]

VIII: REFORM STEP 7: ALLOW MEDICAID BENEFICIARIES TO BUY INTO PRIVATE PLANS

Medicaid enrollees would be free to use their MHCs to join existing employer-provided plans. Given that a significant number of new Medicaid enrollees in the last 15 years dropped family coverage, this could be a low-cost way of offering coverage to these groups. Since many of them are above the poverty level, KM could offer grants to them on a sliding scale, with high amounts for near-poverty and lower amounts for incomes near the arbitrary established poverty level.

Related to this, another possible reform is to allow individuals and small businesses to purchase private health plans from the IPE. This would generate four potential benefits.

First, it could reduce Medicaid enrollments by moving some beneficiaries back into private-sector coverage. Second, it will induce more firms to offer health insurance by lowering the insurance overhead cost that exists in this market. Third, it will also reduce insurance costs by creating a larger pool of buyers with more purchasing power and reduced annual claims uncertainty. Finally, private providers seeking to sell to private firms/individuals could be required to sell in the Medicaid market as well. This will increase the number of firms competing for Medicaid beneficiary dollars.

IX: REFORM VIII: ALL MARKET-DISTORTING PRACTICES AND POLICIES ARE DISCONTINUED

Consistent with basic principles of economics, all market-distorting activities and schemes should be eliminated. These include formularies, Certificate of Need (CON) laws, and state-mandated health benefits above the Medicaid requirements. Providers of medical services would directly negotiate with drug companies for discounts. Elimination of CON laws would allow for easy entrance into the long-term care market in response to market price signals and would reduce costs by promoting more competition among providers.

X: WHAT HAPPENS IN REAL MARKETS FOR HEALTH CARE?

Would the creation of a real marketplace really help Medicaid's beneficiaries and improve Medicaid's fiscal situation? Or is the purchase of health care simply too sophisticated for most people to deal with, especially the poor? Fortunately, we have some evidence on this issue. The Rand Research Corporation conducted a huge study of the impact of financial incentives on the use of medical services between 1974 and 1982. The study included a large group of families and individuals nationwide and included a wide range of family incomes, from as high as $100,000 (in today's dollars) down to the poverty level.

While we are simplifying the actual study here, the basic component consisted of some participants receiving "free" health care while others had to pay a deductible of up to $1,000 (around $4,000 in today's dollars). The conclusion of Rand Researchers:

- "The more families had to pay 'out of pocket,' the fewer medical services they used."
- "The percentage reduction in expenditure caused by cost sharing did not differ strikingly by income group...."

As economic theory predicts, the more something costs, the less of it people will use. Note that the study's low-income participants changed their behavior along with the middle- and upper-income participants.

It is important to note that there were some adverse health outcomes among the low-income participants when they were required to pay some of the cost rather than receiving the services free of charge. For instance, when blood pressure screenings were provided at no cost to the patient, mortality rates declined by about 10 percent. In addition, participants who entered the study with serious symptoms were less likely to leave them untreated when treatment cost was not a factor.

Recall, however, that most of the medical delivery system in this period (1974-82) was a standard fee-for-service plan. Now, the adverse health outcomes cited above could easily be dealt with by HMOs and provider networks which recognize the health and financial value of certain types of preventive care. Indeed, competition among providers for beneficiary dollars would likely raise the quality of care to the poor.

Broad market-based reforms are virtually non-existent in Medicaid. In the past, those in Washington would have looked unfavorably on significant reforms. While attempts have been made to utilize HMOs, these continue to suffer from administered pricing schemes where reimbursements to providers are set too low, causing providers to drop out of the system. Now, however, a new, more receptive attitude in Washington opens up the possibility of dramatically changing the system. Nonetheless, thus far no broad-based reforms have been undertaken at the federal level.

There are, however, several small market-based programs that have shown great success.[9] One of these is the "Cash and Counseling" approach tried in a few states. Florida, for example, operates a program where beneficiaries who are eligible for home- and community-based services receive a monthly budget instead. They may use this to hire caregivers or purchase services. Surveys of participants indicate that 96 percent were "very satisfied" with the service they received, and 97 percent would recommend the program. These are astonishing satisfaction levels!

A similar program in Arkansas called Independent Choices showed a similarly high degree of customer satisfaction, with 93 percent of the participants recommending the program to others. New Jersey has a related program called Personal Preferences. An amazing 99 percent of beneficiaries reported "satisfying" relationships with their caregivers, and 97 percent would recommend the program to others. Does anyone believe that Medicaid's more traditional programs produce these types of outcomes? While such programs are relatively new and limited in scope, we believe the success of "Cash and Counseling" shows that the idea of allowing

beneficiaries to buy their care in the market can work.

While the private sector suffers from many of the same problems as the public sector, we can see how a real market in medical care would operate. Most people did not have prescription drug coverage until the 1980s and 90s. They paid out-of-pocket. The result was a 34 percent increase in drug costs between 1960 and 1980 vs. a 236 percent increase in the general cost of medical care. After drug coverage became much more commonplace, prescription drug costs rose 336 percent vs. 281 percent for general health care from 1980 through 2002.

In cash medical markets such as for cosmetic care, the results are startlingly different. Along with continuing advances in quality, innovations, and comfort, the discipline of the market controls costs. Medical inflation between 1992 and 2001 was three times as high as that of cosmetic care, and these types of services rose in cost at a lower rate than general inflation.

Eye care costs and services where there is not nearly as much third party payment rose at 33 percent between 1990 and 2002, while general medical costs increased at 75 percent. This is in a period when there were dramatic advances in technology and services such as LASIK. In addition, the cost of other types of medical services such as podiatry and chiropractic care (which are often not insured) rose at 43 percent between 1990 and 2002.[10]

XI: SUMMARY AND CONCLUSION

Kansas Medicaid is in serious trouble. It produces a quality of health care that is increasingly unsatisfactory and its long-run fiscal situation is unsustainable. Its problems exist because of the lack of a real marketplace for medical services for beneficiaries. Price controls are inherently inefficient. Any plan for reform needs to address this fundamental flaw. If changes are not made the fiscal state of the plan will only worsen. The State of Kansas faces the unappealing situation of huge cuts in other government spending and tax increases that would wreak havoc on its economy. No reform would inevitably mean even worse health care for enrollees down the road.

Kansas should move now to reform its troubled plan. It needs to create a real marketplace where buyers act in their own interest and providers have an incentive to deliver quality care in a cost-effective manner. This involves creating a mart (an Insurance and Provider Exchange) where beneficiaries buy services from competing prepaid providers with risk-adjusted credits (Medicaid Health Credits) provided by Medicaid. Providers would be allowed to tailor plans for Medicaid's diverse population and Medicaid would reinsure smaller plans to promote competition in both urban and rural areas. All beneficiaries would also receive accounts (Reverse Health Savings Accounts) where they would essentially be paid for engaging in healthy and/or low cost behavior. The resulting outcome will be lower cost inflation in the future combined with better care for beneficiaries.

ABOUT THE AUTHOR

Michael Bond, Ph.D., is a an adjunct scholar with The Flint Hills Center for Public Policy, a fellow at the National Center for Policy Analysis and a professor in the Department of Finance at Cleveland State University.

NOTES

[1] For more information on the budget crisis facing Medicaid, see the "Medicaid Handbook" section of The Flint Hills Center's website. This report builds on two other reports recently completed by Dr. Bond on the subject of Medicaid reform for The Flint Hills Center. For these and to access the Medicaid Handbook, please visit: http://www.flinthills.org/.

[2] "Satisfaction with Own Health Insurance Remarkably Stable," press release (Rochester, NY: Harris Interactive, 29 March 2004). According to the Harris poll, "There are now only modest differences in the levels of dissatisfaction with employer-provided, privately purchased insurance and Medicare programs. However, Medicaid beneficiaries are more likely to be dissatisfied, with 36% of them rating Medicaid D, E or F, 27% not recommending Medicaid to healthy friends and family and 33% not recommending it to those who have serious or chronic illnesses." Available at: http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=781.

[3] Dr. Bond recently completed a review of other state actions. See Michael Bond, "Reforming Medicaid in Kansas: What are Other States Doing?," The Flint Hills Center, 16 January 2006.

[4] Michael Bond, "What's Wrong With Medicaid in Kansas?," The Flint Hills Center, 26 December 2006.

[5] See eBenX (http://www.ebenx.com/) and DxCG (http://www.dxcg.com/) for two firms that have developed software for risk-adjustment.

[6] See Matthew J. Eichner, Mark B. McClellan and David A. Wise, "Insurance or Self-Insurance?: Variation, Persistence, and Individual Health Accounts," NBER Working Paper 5640 (Cambridge, MA: The National Bureau of Economic Research, June 1996). Available at: http://www.nber.org/papers/W5640.

[7] For an alternative view on this point, see Devon Herrick, "The Future Of Health Care For Kansans," The Flint Hills Center, 14 February 2005.

[8] For more information on the Estate Recovery program in Kansas, see Roger A. Van Etten and Brian M. Vazquez, "Kansas Estate Recovery Primer," The Flint Hills Center, 22 September 2005.

[9] For more detailed information on this subject, see Bond, "Reforming Medicaid in Kansas: What are Other States Doing?," The Flint Hills Center.

[10] See Michael Bond, "Reforming Florida's Medicaid Program with Consumer Choice and Competition," The James Madison Institute Backgrounder, number 43 (Tallahassee, FL: The James Madison Institute, February 2005). Available at: http://www.jamesmadison.org/article.php/331.html?PHPSESSID=68d249d5c06d5e56fdd4009259ec8580.

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Flint Hills Center for Public Policy

P.O. Box 782317
Wichita, KS 67278-2317
(316) 634-0218
inquiries@flinthills.org
www.flinthills.org

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FLINT HILLS CENTER
FOR PUBLIC POLICY

TEL: (316) 634-0218 Est. 1996 INQUIRIES@FLINTHILLS.ORG

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WHITE PAPER

Minimum Age Requirements for Joining the NMDP Registry

I. Introduction and Background

In recent months, a significant amount of publicity has been focused on NMDP standards requiring that volunteer marrow and blood stem cell donors must be at least 18 years of age. Examples of this publicity include an article appearing in the November 2001 issue of Reader's Digest, regarding a 16-year-old boy's desire to donate marrow to a stranger,[1] and various state legislative initiatives to set the threshold age for marrow donation somewhere under 18 years of age.[2] At least one United States Representative has inquired into federal legislation regarding donation by minors.[3]

In response to increased focus on this issue, the NMDP has readdressed its current standards regarding age requirements for donation. The NMDP's efforts in this regard have included: listening to the views of those who have proposed lower the minimum age requirement; conducting significant research into legal and scholarly sources on the subject of age of informed consent in the areas of medical treatment and research; and obtaining the opinion of a leading medical ethicist. Based on this review, the NMDP ad hoc committee charged with analyzing this issue (the "Committee") has concluded that the current standard requiring that a donor be at least 18 years old remains the proper standard.

An analysis of the issues raised by allowing minors to join the Registry and the conclusions thereto are set forth below. This White Paper addresses (1) the current NMDP standard requiring that a donor be at least 18 years of age; (2) the complex questions surrounding a minor child's ability to give informed consent to a medical procedure often involving a medical research component; and (3) the benefits and risks involved in lowering the current minimum age for donation. Balancing all of these concerns, this White Paper concludes that lowering the minimum age for donation poses unacceptable risks to the minor child, the NMDP, and society at large, substantially outweighing the potential benefits.

II. The Existing Standard and the Need for Informed Consent

A. The Current NMDP Standard

The current NMDP standard with regard to threshold age for marrow donation is set forth at Section 8.0000 of the NMDP Standards. Specifically, Section 8.1100 states that a "Donor shall be between the ages of 18 and 60."

The NMDP age standard conforms to standards regarding the minimum age of donors in 39 other countries across the world.[4] No registry sets the acceptable age limit below age 17.[5]

Senate Public Health & Welfare Committee
Date: Feb 8, 2006
Attachment # 2

The factors upon which these age requirements are based are the concerns inherent in obtaining a valid, meaningful informed consent from a minor child, and appropriate risk-benefit balancing.

These concerns are particularly significant in the context of unrelated bone marrow donation, which often involves medical research as well as the general provision of health care treatment. For example, marrow donation is a voluntary, non-therapeutic surgical procedure. It is most often accompanied by a research component, such as subsequent use of blood samples in research and the like. Furthermore, the physical risks are borne by the donor, while any benefit is enjoyed by the recipient.

B. The Necessity of Informed Consent

As a general matter, the requirement of informed consent protects the autonomy of the individual with regard to health care and research-related decision-making. Simply put, an individual has a right to be informed of the nature and consequences of a particular procedure or treatment, allowing the individual to make a decision that is both knowing, voluntary and competent. This concept is widely recognized in the contexts of health care and research as the "universal expression of respect for persons," reiterated in the Nuremberg Code, the International Bill of Rights, the Council of International Organizations of Medical Sciences' ethical guidelines, and other such pronouncements concerning the ethics of health care and research.[6]

Legally, the concept of informed consent for treatment can be traced to the seminal opinion of Judge Benjamin Cardozo, in *Schloendorff v. Soc'y of N.Y. Hosp.*, who said: "Every human being of adult years and sound mind has a right to determine what can be done with his own body."[7] As such, medical providers and researchers are required to provide the patient/subject with a reasonable amount of information necessary to make an informed decision, in a manner that the individual can understand, including the risks and benefits involved in either rejecting or accepting treatment or participation in research.

C. Minors Are Generally Not Capable of Giving Informed Consent

When dealing with a minor child, the relevant issue becomes whether a minor has the capacity to understand the information provided, reach a reasonable outcome, and, without being unduly influenced by peers, family, or others, rationally make and voluntarily reach a decision.

Traditionally, the law has treated individuals under 18 as incapable of this type of informed decision-making, a conclusion upon which the NMDP's current standard requiring donors to be at least 18 years old is based. Most state legislatures set age 18 as the age of majority following passage of the 26th Amendment to the United States Constitution, which changed the national voting age from 21 to 18 in 1971.[8] Specifically, only Alabama (19), Nebraska (19), Pennsylvania (21) and Mississippi (21)[9] have established an age of majority over 18. With regard to research, Subpart D of the Department of Health and Human Services Regulations for the Protection of Human Subjects, 45 C.F.R. Part 46, which provides for additional protections for children involved as research subjects, follows state laws regarding age of consent. These regulations defer to the applicable state law for legal age for consent when

defining the term "children."[10]

Thus, in the large majority of cases, individuals under age 18 have been deemed incapable of giving informed consent to health care and for participation in research. As such, where children are in need of medical treatment, parental permission is generally necessary for those 17 years of age and younger. Likewise, federal standards require parental permission along with the child's assent before participation of a child in a research study.[11]

1. Problems inherent in parental consent

While proponents of lowering the age of donation to less than 18 often argue that parental consent is a sufficient safeguard for the young donor and an appropriate mechanism to deliver an informed consent, a variety of sources have recognized the inherent problems of parental consent for pediatric care.[12] For example, in 1995, the American Academy of Pediatrics Committee on Bioethics issued a rather comprehensive statement on the difficulties of obtaining informed consent in the pediatric context, inasmuch as minor patients generally do not have appropriate decisional capacity and legal empowerment to give their informed consent to medical care.[13] Moreover, while society would prefer that parental permission in every instance is based upon the best interests of the child, "the need for child abuse and neglect laws and procedures makes it clear that parents sometimes breach their obligations toward their children.[14] Likewise, with the continued metamorphosis of the "traditional" family unit, situations arise where the parents of a child may very well have different, and very strong, opinions with regard to granting of parental consent."[15]

In addition, any dispute between a minor and a parent (or between parents) resulting in a collection delay or cancellation just before a transplant could prove fatal to a patient who has received high-dose chemoradiotherapy. Typically, the patient begins to receive this high-dose chemoradiotherapy at least six days before the donor's marrow is harvested. The typical transplant preparative regimens are termed "myeloablative," which means that they totally destroy (ablate) the recipient's bone marrow (myeloid cells). Thus, in the absence of rescue with prompt infusion of healthy hematopoietic cells, these pre-transplant chemoradiotherapy treatments are lethal. In spite of this, the first duty of minor donor's parents and the physicians collecting the minor's bone marrow is to protect the donor. Physicians who believe the minor donor does not fully comprehend the procedure and its risks, have a duty to stop the collection. Parents, realizing the donor's risk for rare, but significant, complications may withdraw permission at the last minute. In a situation with four or more decision makers, physicians, parents and the minor donor, who must all agree on the planned donation, the potential for last-minute uncertainty is increased. Thus, the parental consent process may add complexity and increased risk to an already serious situation for the patient.

2. The "mature minor" doctrine

The judiciary has responded to the difficulties inherent in the concept of parental consent by creating the "mature minor" doctrine, which recognizes, in limited, case-by-case instances, the ability of a minor to consent to a particular medical treatment in the absence of parental consent, particularly in instances where parental consent may be difficult to obtain, would cause intra-

family conflict, or otherwise will not provide for the best interests of the child.[16] The mature minor doctrine wholly depends upon the discretion of the trial court to make a determination as to whether a particular minor is capable of giving informed consent for medical treatment. Such a determination must be made on a case-by-case basis, inasmuch as in every case the "circumstances are so varied, so complex, and so hard to anticipate that on one could write rules that would accurately guide decision-makers to correct results . . . ."[17] In addition, in no reported instances has the mature minor doctrine been utilized to allow a minor to participate in research without parental permission.

It is against this complex backdrop that the NMDP has analyzed the question of maintaining the current standard (which conforms with the common legal age of majority across the country), or establishing an amended standard lowering the minimum age threshold below age 18, with or without a requirement of parental permission. This analysis focuses on the risks and benefits not only to the minor child, but to the NMDP and society at large as well.

III. Risks and Benefits in Altering the Minimum Age of Donation

The first step in considering whether to lower the 18 year old minimum age requirement, as currently established by the NMDP Standards, is to examine the competing benefits and risks to a minor child resulting from a decision.

A. To the Child

1. Benefits

The benefit of marrow donation to the minor donor is a positive psychological impact; that is, the child donor will likely come away from the donation experience feeling that he or she has helped another human being, possibly saving that person's life.

2. Risks

Notwithstanding the great care and skill demonstrated by those affiliated with surgical collection of bone marrow, any analysis of the risk to a potential donor, minor and adult alike, must begin with the physical risks associated with the collection. Because donation of bone marrow is a voluntary, non-therapeutic surgical procedure, the commonly accepted ethical approach requires that the scrutiny in assessing the propriety of allowing minors to consent be more rigorous than in the context of a necessary, directly beneficial procedure. Subpart D of the federal regulations governing protection of human research subjects puts this approach into practice, requiring significantly more rigorous restrictions on research involving children in cases where the research shows no prospect of direct benefit to the individual research subject.[18]

Specifically, Subpart D establishes four categories of research into which research involving children must be classified. These categories include: (1) research not involving greater than minimal risk; (2) research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject; (3) research involving greater than minimal

risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition; and (4) research that is not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.[19] Subpart D expressly provides that DHHS will not allow research involving children in the absence of heightened protections, increasing in rigorousness from categories (1) through (4), above. For example, research involving children falling under category (4) cannot go forward unless the Secretary of Health and Human Services, after reviewing the proposed research with a panel of experts and providing an opportunity for public review and comment, determines that heightened criteria has been met.

In addition to the risks of collection, the long-term medical effects of some of the procedures potentially used in a donation are not established, and thus create an unknown risk to young donors. Also, in some cases, donors are requested to donate blood products and additional marrow or G-CSF/pheresis stem cells to rescue a patients who have lost their graft or relapsed. This can be a very difficult, complex, and emotional decision that requires a very mature analysis. This could be particularly troublesome decision-making for someone under age 18.

In the context of marrow donation, the direct benefit to the child is arguably negligible when donating for the benefit of an unrelated recipient, and clearly less substantial than when donating to a family member, and carries no direct medical benefit to the donor in either case.

The effect of peer influence, both real and perceived, creates significant concern with regard to the ability of a minor to give informed consent. Peer pressure can make a minor act in an immature manner even though the donor otherwise possesses the required cognitive skills and maturity otherwise necessary to give informed consent. News reports on the subject of minor consent reveal pockets of groundswell initiatives started by high school students in various areas of the country.[20] While these initiatives are most certainly driven by good intentions, the realities of peer influence suggest that children campaigning for access to the Registry may be influenced in some appreciable degree by various peer pressures.

In addition, it is widely believed that priorities and attitudes for purposes relevant to making judgments differ between children and adults. A child, for example, is more likely to be concerned with the short-term effects of a decision (such as the immediate reaction of his/her peers), compared to an adult, who is ostensibly more concerned with a decision's long-range effect. An example of this difference is the widely-held belief that children are more likely than adults to be risk takers, believing they are invulnerable to harm.

B. To the NMDP and Society At Large

In addition to weighing the risks and benefits as to the minor child, this analysis must also consider the risk/benefit analysis to the NMDP with regard lowering the minimum age for donation. In essence, the NMDP must determine whether the benefits would outweigh a departure from the nationwide norm with regard to the age of consent.

1. Benefits

A decision to allow children under 18 to become marrow donors may possibly benefit the NMDP, and society generally, by increasing the numbers and diversity of the Registry. Specifically, as a function of expanding the number of eligible potential donors, the number of individuals on the Registry would likely increase. Since the number of new potential donors is not likely to be large, the significance of this increase is probably not substantial.

2. Risks

This analysis, based on extensive research, has failed to uncover any persuasive precedent for allowing those under 18 to consent to marrow donation and has identified no supportable position for allowing minors to join the Registry. In fact, such a change in policy could subject the NMDP to greater liability exposure.

As discussed above, 18 is the generally-accepted age of majority nationwide. Upon reaching the age of majority, an individual is legally considered capable to giving informed consent for medical treatment. Parents may, of course, consent to therapeutic, necessary treatment as well as research participation on behalf of their children. The problems associated with parental consent (outlined in detail in Section II.C.1, above) are intensified in the marrow donation context, where the procedure is surgical, non-therapeutic, often involves a research component, and does not directly benefit the child. Moreover, while the court system arguably has the resources to administer a "mature minor" doctrine, the NMDP simply is not equipped to engage in this type of quasi-judicial decision-making on a case-by-case basis.

In order to make a satisfactory determination as to whether a particular child is capable of providing informed consent in the medical treatment context, the courts examine each case independently to determine whether the child understand the risks, consequences and nature of the treatment In the event minor children are allowed to become donors, to protect the best interest of the child and the NMDP itself, the NMDP must establish a quasi-judicial decision-making mechanism designed to ensure that each minor donor possesses the cognitive skills and maturity necessary to give informed consent. The administrative burden associated with such a system would be quite heavy.

Finally, the NMDP must be conscious of the potentially negative societal perspective resulting from a decision to lower the minimum age for donation under the generally accepted age of consent. As explained by Jeffrey Kahn, Ph.D., Director of the University of Minnesota Center or Bioethics and NMDP Board member: "If there is a perception that the process is tainted in any way, it will likely affect the public's willingness to participate."[21] Lowering the minimum donor age has the potential to result in a perception that children are being exploited by the NMDP for self-serving purposes (*i.e.,* increasing the number of potential donors on the Registry notwithstanding the costs to vulnerable individuals).

IV. Looking Forward

At the present time, the Committee feels that while retaining the 18 year old minimum

age requirement is the proper course, the NMDP must continue to monitor this issue, gather relevant information, and remain alert to changes in legal and scientific opinion on the matter. The Committee has suggested certain action items in this regard, including:

- Inviting or otherwise encouraging those opposed to the minimum age requirement to provide additional information regarding the issue;
- Including articles in the Marrow Messenger about opportunities for those as young as 18 years old to become members of the Registry;
- Reviewing NMDP recruiting materials for appropriate scripts (re: risk, etc.);
- Educating high school counselors, parents and volunteers working in schools regarding the opportunity to donate at age 18;
- Remaining alert to changes in legislation regarding age of consent at the state level; and
- Asking 16- to 18-year-olds to volunteer at blood drives to give blood or otherwise volunteer time with blood centers, file maintenance, etc.

V. Conclusion

After extensive analysis, the NMDP Committee has determined that the current standard, setting the minimum age for donation at 18 years old, is the appropriate standard. In the vast majority of instances, an individual must be at least 18 years of age to legally consent to medical treatment and to participate in research (in the absence of parental permission). In the case of marrow donation, where the procedure is surgical and non-therapeutic, and often involves a medical research component, a persuasive rationale for lowering the minimum age below 18 simply does not exist, particularly in light of potential exposure to liability. As such, the current standard should remain unchanged.

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[1] Rebecca Cook, *Everyday heroes: Blood Brother,* READER'S DIGEST, 25-28 (Nov. 2001).

[2] *See, e.g.*, Wash. Rev. Code § 70.54.305 ("A person's status as a minor may not disqualify him or her from bone marrow donation"); *see also, e.g.*., Martin Luttrell, *Students Push to be Marrow Donors*, WORCESTER TELEGRAM & GAZETTE, October 11, 2001, at B5 (outlining high school students' attempts to persuade Massachusetts state legislature to pass law lowering minimum age for marrow donation).

[3] By memorandum to NMDP legal counsel, dated January 21, 2001, Isaac A. Fordjour, NMDP Legislative Representative, reported that U.S. Representative Tom Osborne (NE) contacted the NMDP regarding possible federal legislation to allow minors to donate marrow. Representative Osborne did not pursue the issue following a November 2000 meeting between Mr. Fordjour and Representative Osborne's staff.

[4] *See* October 17, 2001 memorandum of Amy Burger, NMDP Communications and Education, ¶ 2

[5] *See id.*

[6] Lawrence O. Gostin, J.D., *Informed Consent, Cultural Sensitivity, and Respect for Persons*, 274 JAMA 844 (Sept. 13, 1995).

[7] *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92 (N.Y. 1914).

[8] *See*, Lawrence Schlam & Joseph P. Wood, I*nformed Consent to the Medical Treatment of Minors: Law and Practice*, 10 Journal of Law-Medicine Health Matrix 141, 148 (Summer 2000).

[9] Note, however, that while the age of majority in Mississippi is 21, the age of consent for health care is 18.

[10] *See generally*, 45 C.F.R. Part 46, Subp. D; *see* 45 C.F.R. § 46.402(a) (defining "Children").

[11] *See, e.g.*, 45 C.F.R. § 6.408.

[12] The American Academy of Pediatrics Committee on Bioethics has discarded the term "parental consent" in favor of "parental permission," inasmuch as: We now realize that the doctrine of "informed consent" has only limited direct application in pediatrics. Only patients who have appropriate decisional capacity and legal empowerment can give their informed consent to medical care. In all other situations, parents or other surrogates provide informed permission for diagnosis and treatment of children with the assent of the child whenever appropriate."

[13] *See id.*

[14] *See id.*

[15] *See, e.g., Curran v. Bosze*, 566 N.E.2d 1319 (Ill. 1990) (where father of children sought to compel mother to give consent to marrow harvesting procedure). This reality is further recognized by Subpart D to DHHS' regulations for the protection of human subjects, 45 C.F.R. Part 46, which generally require parental permission from both parents in cases where the proposed research involves greater than minimal risk. See 45 C.F.R. § 46.408.

[16] See, Lawrence Schlam & Joseph P. Wood, *Informed Consent to the Medical Treatment of Minors: Law and Practice*, 10 Journal of Law-Medicine Health Matrix 141, 151-52 (Summer 2000) (citations omitted).

[17] *See id.*

[18] *See* 45 C.F.R. §§ 46.405 - 46.407.

[19] *See* 45 C.F.R. §§ 46.404 - 46.407.

[20] *See, e.g.*, Martin Luttrell, *Students Push to be Marrow Donors* , Worcester Telegram & Gazette, October 11, 2001, at B5; Rebecca Cook, *Everyday Heroes: Blood Brother*, Reader's Digest, 25-28 (Nov. 2001).

[21] *See* October 17, 2001 memorandum of Amy Burger, NMDP Communications and Education, ¶ 4.