

Family Violence Prevention Fund

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From: Lisa James, Director of Health and Lonna Davis, Director of Children's Programs, Family Violence
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Re: A Potentially Disparate Impact on Survivors of Domestic Violence in the Proposed Criteria for
Evidence of Effectiveness of Home Visiting Program Models

Date: August 17, 2010

The Family Violence Prevention Fund works to prevent violence within the home, and in the community, to help those whose lives are devastated by violence because everyone has the right to live free of violence. For more than three decades, the Family Violence Prevention Fund (FVPF) has worked to end violence against women and children around the world. Instrumental in developing the landmark Violence Against Women Act passed by Congress in 1994, the FVPF has continued to break new ground by reaching new audiences including men and youth, promoting leadership within communities to ensure that violence prevention efforts become self-sustaining, and transforming the way health care providers, police, judges, employers and others address violence. We house the DHHS designated National Health Resource Center on Domestic Violence that provides technical assistance nationwide on the intersection between health and domestic violence.

The Patient Protection and Affordable Care Act's investment of \$1.5 billion to develop and implement Early Childhood Visitation models is an extremely important step in improving the maternal and child health and safety in our country. Home visitation programs have been effective in improving maternal health, reducing child maltreatment and improving child health outcomes.

For these reasons, we are tremendously encouraged by the thoughtful and thorough criteria of evidence of effectiveness of home visiting models as appeared in the Federal Register on July 23, 2010 (hereafter "the Notice").

As noted in our recent policy brief, *Realizing the Promise of Home Visitation: Addressing Domestic Violence and Child Maltreatment*, "Current evaluations of home visitation models have found that, while

up to 48 percent of the women surveyed who receive home visiting services have reported incidents of domestic violence, few programs have developed, implemented and tested interventions specifically designed to address the trauma these families experience.”ⁱ There is a strong link (described in greater detail below) between domestic violence and child abuse and neglect, poor maternal and child health outcomes, and poor educational performance. Program models that do not explicitly attend to domestic violence may find their effect dampened by the impact of domestic violence. The promise of home visiting cannot be accomplished without specific attention to this population. Knowledge about domestic violence and how to support survivors *must* be integrated into home visiting program models, as we have outlined in a companion brief and memoⁱⁱ.

This is not just a program design issue. In reviewing the Notice, we found several areas where our expertise leads us to believe there may be some unintended, harmful consequences of the application of the proposed criteria for evidence of effectiveness, with consequences disproportionately borne by women and families experiencing domestic violence and/or reproductive coercion and control. In other words, the proposed evaluation criteria may actually constrain HHS’s abilities to achieve its own laudable social goals.

In this memo, we explain how the proposed criteria may *decrease* the likelihood that programs appropriate for domestic violence survivors will join the pantheon of “evidence-based programs,” no matter how urgently these programs are needed. The understandable desire to fund programs proven with specific evaluative technologies so as to minimize risk to the taxpayers and to those who seek government-funded services actually serves to increase the risks to women and families experiencing domestic violence, whose challenges are the most complex and urgent, and who therefore require complex interventions, which are themselves harder to evaluate.

In summary:

Evaluative tools matter: An improper fit between methodology and the intervention being evaluated may render an erroneous verdict about whether something “works.” There is no single evaluative methodology that is best in every situation; what is important is to clearly and objectively understand the strengths and weaknesses of different research tools, and to match the intervention under study with the study design best suited to illuminate what works, to what degree, under what circumstances, and for whom. Given the limitation the statute places on methodologies considered highly rigorous (RCTs and QEDs), it is imperative that in this limited “toolkit,” both methodologies are on equal footing in a general sense, with the particulars of the intervention determining which approach is to be favored.

Those already being hurt may be further harmed: The ranking of evaluative tools creates incentives to fit the task to the tool—to shape program designs so that they are a best fit with preferred evaluative methodologies, rather than finding the most rigorous and relevant evaluative tools for a given model. The result can marginalize program models that serve those

who themselves are the most marginalized: participants whose lives are the most complex and shifting.

Indeed a strong case made for moving beyond in general has been advanced by a number of respected scholars;ⁱⁱⁱ here, we focus on the disparate impact on families experiencing domestic violence. Favoring clear, elegant solutions provides a strong disincentive to evaluate models that hold this complexity, even if they may be best positioned to work with a large group of women in need of services. As such, in section II we describe how RCTs and QEDs may actively select against models that work with domestic violence survivors; in section III we offer some suggestions for criteria HHS might consider in addition to what it has already proposed.

The comments that follow describe modifications to the proposed criteria for evidence of effectiveness necessary if survivors of domestic violence are to be adequately represented in evaluation research and program design. We also give feedback in several areas where HHS has explicitly invited comments. We believe addressing the issues described below will significantly increase the probability that HHS, through the states, will find, fund and scale those home visiting models most likely to meaningfully, sustainably and measurably “assure coordination and delivery of critical health, development, early learning, and child abuse and neglect prevention services to most effectively serve [at risk] children and families.”^{iv}

I. The need for careful consideration of relevance and rigor in evaluating interventions

The comments in this section are in direct response to section 3.1 *Criteria for Well-Designed, Rigorous Impact Research*. Taken together, the preferences (discussed below) for RCTs and low attrition rates, and the need to consider motivation make it questionable whether urgently needed program models that integrate domestic violence expertise into home visitation will be adequately represented in those that have proposed levels of evidence.

A. The preference for Randomized Controlled Trials (RCTs)

The statute indicates that 75% or more of funds to any entity are to be directed to interventions that have significant, and in some cases, sustained, positive outcomes in a number of specific domains, “when evaluated using well-designed and rigorous—(aa) randomized controlled research designs, and the evaluation results have been published in a peer-reviewed journal; or (bb) quasi-experimental research designs.” As such, the statute makes no value judgment between these two evaluative methodologies. HHS has, however, clearly articulated a strong preference for RCTs, suggesting that they are the “gold standard”¹ and that their application avoids selection bias and other problems that

¹ While the Notice does not give specific preference to “high” over “moderate” quality impact studies, the language itself carries a clear message: RCTs are the preferred evaluative methodology. If RCTs are held as the gold standard, models may be reverse-engineered to best fit the preferred methodology, not the needs of highly stressed families. Who, after all, sets his or her sites on second place?

may be more inherent to quasi-experimental design studies. We do not disagree with the specific points made in the Notice about a potential for bias, but suggest that there are additional considerations, which might cause the relative merits of these two evaluative approaches to be weighed differently. Furthermore, we suggest that these limitations may have a disparate negative impact on families experiencing domestic violence.

i. "System-experienced" participants may react to being chosen or not in a manner which is an unpredictable artifact of experimental design

Unlike medical drug trials, there is no double-blinded placebo in randomized controlled trials of social interventions. However clear it is to a researcher that who is assigned to a treatment group and who to a control group is not based on merit or attribute, this clarity may not be experienced by an individual who may well feel personally "chosen" for something new and special (how often for recruitment purposes do researchers play up the importance of a project—it is called recruitment for a reason)—and those randomized to the control group may feel they were "not chosen." Domestic violence victims, particularly those in poverty, have too often found formal services and systems reluctant to engage with them, and the continual dead-ends and denials of services can reinforce the sense of powerlessness many survivors feel.^v Being recruited to a study population and then denied that treatment may be experienced as another false promise made by "the system," no matter how much informed consent is obtained. These experiences condition people's responses, and may lead to underperformance of a control group; or, the control group might overcompensate instead. This "resentful demoralization,"^{vi} whichever direction it takes, is a reaction to the experimental design, independent of the program being evaluated and can distort effect size. "[U]nfortunately, it is difficult to predict *a priori* the direction or extent of such bias."^{vii} Such bias has no parallel in the real world, undercutting the external validity that is of critical importance if quick, broad, implementation of home visitation is to occur productively. From a safety perspective—for mother and child— we can ill-afford to buttress the experiences of abused women involved in multiple-systems: that systems are capricious, uninterested in their welfare and even abusive. Reinforcing these traumatic experiences introduces harm into the evaluation process, separate from the intervention. It is a harm that can be avoided through well-designed QEDs.

ii. Systemic context needs illumination in evaluating programs that work to integrate or be a gateway to other services

The statute requires that states conduct needs assessments to identify communities with concentrations of a wide range of issues and situations that often coincide with child abuse and neglect, including (but not limited to) poverty, crime, domestic violence, high rates of high-school drop-outs, substance abuse, and unemployment. These are issues generally under the purview of a range of departments (differently configured in each state), including education, public health, justice/corrections, public welfare, medical, and labor and training. The strengths,

weaknesses, policies, and inclinations of these systems in a given state may be significant factors in whether a model undertaken within its borders succeeds or fails. In the absence of a systemic analysis, it is difficult to differentiate between necessary and sufficient. Sometimes the best interventions are those that enhance existing interventions, but neither alone will demonstrate impact. Because randomization occurs *within* a geographic area and within a particular ecosystem of systems, not *across* it (i.e., we don't relocate people as part of randomization of home visiting studies), the RCT is likely to obscure the import of these interactions.² In these cases, quasi-experimental methods are preferable, as there are more explicit opportunities for cross-community comparison, which may force the articulation of contextual differences that could explain an effect or the absence of an effect. This is vital to building external validity—the question of how robustly outcomes will hold across contexts. As a key purpose of this legislation is to dramatically increase the number and quality of home visiting models across the states, we must recognize that questions of “what works” really are questions of “what works, for whom, where, and under what circumstances,” where circumstances are heavily informed by systems.

This recognition of the role of systems is particularly relevant for cases involving domestic violence and/or reproductive control. Again, it is vitally important that home visitation programs integrate domestic violence expertise *into* their models. Coordination with domestic violence providers will be grossly inadequate. Nonetheless, few, if any, of these cases are likely to (or should) be handled entirely by even the best-trained home visitor. Congress clearly understood the complexity of these women's lives, as reflected not only in the variables it directed be assessed in initial needs assessments, but in the explicit statement that one of the three purposes of home visiting programs is to “improve coordination of services for at risk communities.”

- iii. *Evaluations of home visiting programs on sub-populations must recognize the high levels of domestic violence within these subpopulations and must evaluate models' addressing domestic violence in the context of other issues*

States are required by the statute to provide “a statement identifying how the selection of the populations to be served and the service delivery model or models that the entity will use under the program for such populations is consistent with the results of the statewide needs assessment.” **In each of the priority populations named in the statute, domestic violence victims are disproportionately represented. Domestic violence is correlated with each issue and with compromised outcomes.**

² While RCTs can theoretically include external factors that influence outcomes, they really can only do so if external factors themselves can be included in the randomization. If, for example, a juvenile delinquency diversion program is tested in counties with high “buy-in” from judges for a diversion program, it may have a markedly different effect from work in counties where judges vary widely in their willingness to send youth to diversion (but all judges on paper are following the same protocols). But the randomization in the first case is all within a setting where judges are on board. While solid research would theoretically surface this as a core assumption of the model, it often doesn't.

- (A) Eligible families who reside in communities in need of such services, as identified in the statewide needs assessment required under subsection (b)(1)(A) [this section specifically mentions domestic violence].
- (B) Low-income eligible families: Couples who report domestic violence are more likely to be economically vulnerable and live in disadvantaged neighborhoods.^{viii}
- (C) Eligible families who are pregnant women who have not attained age 21: Adolescent girls in physically abusive relationships are **3.5 times more likely** to become pregnant than non-abused girls.^{ix}
- (D) Eligible families that have a history of child abuse or neglect or have had interactions with child welfare services: The risk for child abuse is **3 times** higher in families where there is domestic violence.^x
- (E) Eligible families that have a history of substance abuse or need substance abuse treatment: Abused women are at increased risk for substance abuse including alcoholism; **2.6 times** more likely to use tranquilizers, sleeping pills, or sedatives; **3.2 times** more likely to use anti-depressants, **2.2 times** more likely to use prescription pain pills. Abused pregnant women are more likely to drink during pregnancy and adolescent victims of abuse are also at increased risk for alcohol, tobacco, and substance abuse, as are perpetrators of abuse.^{xi}
- (F) Eligible families that have users of tobacco products in the home: Victims of domestic violence are **2 times** as likely as non-abused women to report current tobacco use. One-half of women who reported domestic violence in the past year were current smokers, as compared to one-quarter of women who did not disclose abuse.^{xii}
- (G) Eligible families that are or have children with low student achievement: Childhood exposure to domestic violence increases the likelihood of more school nurse visits, referral to a school speech pathologist, frequent school absences, lower grade point averages and school suspension.^{xiii}
- (H) Eligible families with children with developmental delays or disabilities: Children exposed to domestic violence are at significantly higher risk for: Posttraumatic Stress Disorder, depression, anxiety, developmental delays and aggressiveness.^{xiv}
- (I) Eligible families who, or that include an individual who, are serving or formerly served in the Armed Forces, including such families that have members of the Armed Forces who have had multiple deployments outside of the United States: 23% of men on Active Duty in the military perpetrated domestic violence in the past year; 28% - 30% of Active Duty and veteran women have been victimized in the prior year.^{xv}

Effective interventions *must* therefore attend to domestic violence—not as a separate issue simply to be referred out to a specialist, but one that is addressed in the context of home visitation, even as they link to other systems.

Given the prevalence of domestic violence within other target populations, the impact on outcomes must be considered as HHS ranks programs. For example, outcomes related to increased spacing between birth, which in general are tied to better outcomes for mother and child, reflect an expectation of agency on the part of the mother around reproductive choice that is absent for many women in abusive relationships. Victims of domestic violence are significantly more likely to experience rapid repeat pregnancy^{xvi} and report high levels of forced sex, birth control interference and difficulty negotiating contraceptives in the context of abusive relationships.^{xvii}

It is difficult to conceive of a scenario where the strength and preferences of the systems that surround the home visitation program—particularly those that address child welfare and domestic violence, where harms are imminent and potentially lethal— are not assessed as integral to an evaluation and to any evaluation of that evaluation. Yet this is well beyond the purview of an RCT (and most QEDs as well, but QEDs lend themselves to somewhat more systemic analysis as described above).

With so many caveats and concerns about RCTs, we suggest that they not be the gold standard with QEDs as runner-up. We further suggest that there not be a gold standard methodology, as researchers and program designers should be dedicated to producing the most rigorous and relevant studies. Certainly, the standards of evidence should not place restrictions on the types of evidence to be considered beyond those required by statute.

B. The preference for low attrition

Attrition is a significant issue for home visiting programs in general, although evidence suggests that models with more outreach have lower attrition.^{xviii} We are particularly concerned about the implications for abused women in HHS's suggestion that minimal attrition be a condition for a rating of "high." While from a validity standpoint, minimizing attrition is an important concern, without the potential for reasonable exceptions, women living with violence are likely to be screened out of trials and interventions.

Home visitation programs are intended to support women and children in unstable situations. When abuse is present, instability and uncertainty are significantly enhanced, both by relationships and by the demands of multiple systems in which many women parenting in the context of violence are involved. Any researcher doing screenings will realize that there are a high number of other issues and potentially confounding factors in these women's lives (even if they don't self-identify as abused, or disclose abuse—see above summary of the overlap between domestic violence and other challenges), and as such, may well screen them out of

studies—all those confounding factors increase instability that undercut study completion, in addition to increasing analytic complexity and uncertainty.

If a pregnant or parenting woman discloses abuse during screening, a reasonable researcher would assume (if this person has been paying attention to public health messages over the last two decades) that the woman will be encouraged to leave her situation as part of the intervention, entailing a move and therefore a lowered likelihood of completion. (Whether this is a correct assumption is beyond the scope of this memo.) A researcher seeking low attrition is likely to disallow her participation, based not on a clinical concern, but based on an externally imposed methodological preference.

It is worth noting that if she gets into the study, she may well stay in the relationship (and the geography) and still not complete the program. Abusers sabotage not only birth control, but access to therapists, services and more. Models that can hold this complexity exist. We need more of these models, and yet we are less likely to have access to them given the standards of evidence, since these models are less likely to be funded.

C. Not studying the role of motivation.

“The families that choose to participate in programs, and the communities that welcome participation in community-wide interventions, may be different from families or communities that do not choose to be involved.”^{xix} Parental motivation is a key element most home visiting models draw on. It is worthwhile to study the role of motivation directly, rather than controlling for it.

RCTs and QEDs are absolutely relevant in many situations. However, we strongly advocate for the restoration of equal footing for QEDs and RCTs as in the statute and therefore a re-construction of the high/medium evidence criteria.

II. The need for more complete evidence to ensure that women and children experiencing domestic violence have access to interventions that help them.

As much as restoration of equal footing between RCTs and QEDs is important, this alone is insufficient if we are to understand, refine and promote the range of interventions necessary for the legislation to achieve its aims and for meaningful change to be possible in the lives of disadvantaged children in this country. As described above, RCTs and QEDs alone may lead to favoring studies where individuals face the fewest confounding conditions, whether individual (e.g., coincident chronic illness) or systemic (e.g., involvement in other systems). If RCTs and even QEDs are the sole doorway to a “high” rating of evidence of effectiveness, those who stand to lose the most are those who have the greatest need.

Each of these harms can and should be assertively avoided by HHS. Opportunities exist to adjust the criteria for current and future funding. We recognize HHS has no authority to change the statute, but there is an opportunity for supporting states in choosing interventions that meet the criteria for the 25% of funds that can be expended on promising interventions, and that meet the needs of survivors of domestic violence. We urge HHS to consider issuing additional evidentiary guidelines to states to encourage seeking out and studying interventions that explicitly target domestic violence survivors (and therefore embrace a degree of complexity and systemic interference that other models may not) or that have the capacity to support domestic violence survivors without limiting their program to women willing to take on this label; specific recommendations for evidence criteria are included in section III. These programs should, we have argued in a companion memo^{xx}, be heavily funded with the 25% of dollars that can be invested in promising interventions with a growing, but not yet strong, evidence base.

We turn here to issues that neither RCTs nor QEDs, alone or in combination, cannot fully address, and which must be addressed to meet the needs of mothers and children experiencing domestic violence: pressure to “cream;” generalizability and adaptation; and evaluation and rapid scaling.

A. Those with multiple challenges, who are disproportionately experiencing domestic violence are often excluded from experimental and quasi-experimental studies

The potential for “creaming ” is significant and real, and may further marginalize and harm populations who most need effective services, as they are the first to be screened out of experimental design studies because they face multiple challenges. On the practice side, creaming is presumed to assure better outcomes, faster, as those who are easier to help are helped. On the evaluation side, creaming can be seen as getting a clean sample. But as discussed in IAii and IAiii above, women who face domestic violence rarely face only domestic violence. Their involvement in a research study can therefore introduce multiple confounding variables that can be seen as weakening the validity of the study itself. This is the micro expression of the multiple systems response, but the need for explicit evaluative attention is different. Systems can be discounted and ignored in a study, to its detriment. Women can be excluded for methodological, not clinical, reasons and the result could be dramatically increased danger. Yet it is these very factors that home visiting programs seek to impact. For example, domestic violence is a significant risk factor for compromised maternal health, including: gastrointestinal disorders, eating disorders, neurological problems (fainting or passing out, severe headaches, vision and hearing problems), urinary tract infections; chronic neck, back and pelvic pain; migraines and other frequent headaches.^{xxi} There is a significant overlap in prevalence between HIV and domestic violence, which may be due in large part to the danger in some battered women’s negotiating safe sex behavior; abusive men are more likely to have other forced vaginal sex and sex without a condom which increases the chance of transmission; violent victimization increases HIV risk behaviors, including IV drug use.^{xxii} Battered women report more health risks during pregnancy and have worse pregnancy outcomes. Women experiencing abuse in the year prior to and/or during a recent pregnancy are 40 to 60 percent more likely than non-abused women to report high-blood pressure, vaginal bleeding, kidney or urinary tract infections, hospitalization during pregnancy, and are 37% more likely to deliver preterm. Children born to abused mothers are 17 percent more likely to be born underweight, and are more than 30%

more likely than other children to require intensive care upon birth.^{xxiii} The co-occurrence of challenges, including challenges that force women to drop out of an intervention or study, are data that need examination, rather than dismissal as irrelevant.

B. External validity when systems, context and complexity are considered

The statute opens the door for significant expansion of home visitation nationally. The celebrated diversity of the United States' people and places requires we focus on external validity as much as internal validity if rapid scaling is to be successful. As such, it is vitally important that the models endorsed for replication via HHS's criteria process have generalizability, and that limits to generalizability are understood. As the General Accounting Office noted in a 2009 report, "As social interventions become more complex, representing a diverse set of local applications of a broad policy rather than a common set of activities, randomized experiments may become less informative."^{xxiv}

"In most cases, more disadvantaged children are likely to realize the greatest benefits. In some cases, however, children who face the greatest number of risks may require even more specialized services, so they may benefit less from a particular program than children who face only a few risks."^{xxv} This finding of the RAND Corporation supports the assertion that those with the most challenges require interventions that link across systems (as Congress intends funded home visitation programs to do). RCTs and QEDs are insufficient in this regard. Evaluations that examine the context of systems to give insights into external validity and to help us understand the potential and limits of a given model for highly stressed families are needed and unavailable unless the evaluation toolbox is thoughtfully expanded.

If we are serious about better outcomes, presumably a significant reason for rigor in our evaluations, we must ensure that survivors of domestic violence are not screened out because the complexities of their individual situations cloud the clarity of a study's findings, as there is indication that models not adapted to their needs have little to no effect.^{xxvi} In scaling such a model, either these women will be denied services because they do not fit the target population, which we suggest leaves some of the most vulnerable children in need of services; or they will be placed into programs where well-intentioned, but uninformed or ill-equipped home visitors may actually increase the danger and volatility in the home. Both of these are grossly unsatisfactory outcomes.

C. Adaptation

Working with violence survivors will require adaptation and ongoing evolution of models; evidence criteria should favor exposure and analysis of adaptation. We are very pleased that HHS will be helping states balance the need for evidence of what worked in the past with the need to adapt practice to ensure relevance for the future, and continuously improving practice, as briefly described in 8.0 Future Considerations.

A more complete approach to evidence will certainly reduce the barriers to creating and testing interventions that are better fits for survivors of domestic violence. However, no two communities are alike, and cookie-cutter replication rarely works. Adaptation is necessary because political, social, funding, cultural and other contexts, as well as the ecosystem of interventions that a given organization is part of, vary wildly from one community to another. Adaptation of a proven model is also often necessary, paradoxically, to ensure the fidelity of the model because the larger context changes, and what really needs to be replicated is the interplay between a context and an intervention. Current frameworks that value absolute consistency and force adaptation under the radar screen emphasize proving at the expense of improving, and deprive the field of urgently needed knowledge. What constitutes capacity to adapt a model to maintain or improve results in changing contexts is poorly understood.

Usable knowledge is significantly lacking about when adaptation is advantageous, when it is deleterious, and how organizations determine when and how to adapt. Even so, adaptation happens—evaluative methodologies that help inform how and when to adapt models are needed; as described below, if this information is not systematically collected and valued, domestic violence survivors will be disparately impacted.

Adaptation of a studied model is called for (and occurs whether or not it is sanctioned) in a number of non-exclusive situations. Even prior to this landmark legislation, “The characteristics of state-based home-visiting systems vary from one state to another and from one home-visiting program to another, depending on the way they were implemented, the state’s particular administrative structure and political climate, and the home-visiting programs’ traits, among others.”^{xxvii}

- a. States need guidance when their systemic and policy contexts do not mirror those in a model’s study setting, and they have concerns about simply adopting a rigid model. As noted in IAii, this is particularly important for interventions that serve to fill in and around other systems, providing essential support and assistance, as well as coordination, as do home visitation programs. Again, domestic violence survivors often sit at the nexus of unaligned systems, with different gaps and opportunities in each state and locality. The impact of a failure to mindfully adapt will be particularly profound for them.
- b. Changes in the landscape can be dramatic, even in one place. The last several years have wrought havoc on state’s safety nets. Each state makes different trade-offs and compromises, but in most of the country, the cuts are deep and painful. States need guidance not only on what models to adapt, but in how to adapt them. For example, if the population needing services doubles and the funds don’t, should dosing be halved to serve everyone, or should only half the people needing services be served?
- c. The awareness that there are no one-size-fits-all solutions to social problems is now high. As such, many models are now being rigorously tested among subpopulations. However, adaptation is generally made based on individual identity (and often demographics; this is reflected in what are considered for baseline equivalence). Certainly, this is preferable to no adaptation, but the effect of an intervention must be tailored to more than the demographics of

its clients. Matching on race and ethnicity, and socioeconomic status alone^{xxviii}—minimum requirements for the moderate rating in the Notice—obscures the different experience of being a young Latina mother, born in Mexico and now living in San Diego, with an annual income of \$11,500 and the experience of a woman who is also a young Latina mother with an annual income of approximately \$11,500 who lives in Portland, Maine who is a third generation resident of the United States. Furthermore, identities change, particularly regarding violence. Domestic violence and reproductive coercion are dynamic realities; some relationships are in a difficult to define gray zone, or the level of abuse changes over long periods of time. Yet as states work to rapidly scale existing models, the required adaptation needs to be heavily guided by research. States simply cannot wait for every subpopulation to be studied in a range of settings. If they do, again, interventions that work with a particularly complex range of issues may well be the last studied. As described above, those with the most complex issues are often those experiencing domestic violence.

- d. The more co-occurring issues a family faces, the more services need to be tailored. Even in a service-rich environment, information and referral alone is no way to adequately address impacted problems like domestic violence; the more issues, the more tailoring is needed. It may also be that the less service-rich the system ecology is, the more tailoring is required. Either way, working with domestic violence survivors often requires improvisation; rigid service models are increasingly falling out of favor. Experimental designs are a poor fit for complex interventions with multiple moving parts that require practitioners and participants to choose a unique combination of services and supports from a range of them, rather like picking from a pantry, and thus have very individualized “dosing” and “treatment protocols.” Responding flexibly may mean deviating from standard, tested practice. The more risk factors a child and/or family face, the more such deviation (which can more favorably be called tailoring) is likely to be necessary^{xxix}; experimental design can offer no guidance about deviation from protocols, and when deviation may be mission enhancing or mission eroding. And, again, domestic violence victims and their children experience a depth of enmeshed challenges that makes them particularly vulnerable when knowledge about adaptation and tailoring is lacking.
- e. Models evolve over time as context changes. Some evolve rapidly. Experimental methodologies cannot maintain validity if interventions under study evolve fluidly—following different protocols at the beginning and end of a trial because mindful adaptation to changing context or to information that helps improve quality indicates the need for changing protocol. Randomization is based on individual characteristics, when there is strong and broad evidence that context—social context, and the availability of other community resources—both formal social services, and informal social support—is important in the prevention of child abuse^{xxx}. Even interventions that target the individual may actually be most effective when the individual interacts with other individuals who are in the same “treatment” *and may have positive spillover to others*, essentially creating or reinforcing new social norms. This is relevant to evaluation, because it suggests that the conditions in a community relevant to the study will change over time, and may require a changed program protocol.^{xxxi}

D. Scaling

Implementation of the statute will require a rapid scale up-across the country. It is a real danger that states, recognizing the need to adapt models somewhat, will make unfounded adaptations based on urgent necessity, not on data and research. This is dangerous, but dictating no adaptation is unrealistic.

Bringing home visitation to scale can meaningfully and effectively occur only with the pairing of what can be generalized and what should be adapted to context (and how that adaptation can occur). Particularly if we are to support meaningful change in the most challenges lives, these are challenges that must be met with evidence, and a kind of evidence we are unlikely to get, certainly at a scale and in a timeframe necessary, through RCTs and QEDs alone.

III. A more complete approach to evidence will enable the surfacing and scaling of interventions that meet the needs of domestic violence survivors

These comments are directly related to 7.0 Future Allocations Based on Application Strength and 8.0 Future Considerations

“When home visiting programs fail to address domestic violence or use inappropriate interventions, they also run the risk of undermining their overall effectiveness,”^{xxxii} as domestic violence during pregnancy and early parenting is highly correlated with many of the challenges that home visiting seeks to address. As such, domestic violence and reproductive coercion and control are not coincident issues requiring simply a referral by the home visitor to more service; **addressing these issues in the context of the intervention itself is integral to realizing home visitation’s promise for fragile families.** Evidence of effectiveness must integrate this practice reality directly, particularly given that domestic violence is endemic among families in home visiting. We therefore suggest that studies be explicitly rated by their effectiveness for families where domestic violence is present.

The danger that methodological considerations may be favoring certain populations should be compensated for. We suggest that criteria of effectiveness for the 25% of dollars not currently required to be invested in “evidence-based” programs be specifically designed to assess effectiveness for program types that are poor fits for RCTs and QEDs alone. We encourage HHS to build the capacity of funded entities to use newer evaluation technologies to discourage selecting participants with clearer-cut cases, who are most likely to stick with treatment and whose needs can be met well by existing service providers.

We suggest that the following evidence criteria be used to support the identification and ranking of more promising programs (the 25%), should it be possible to create a separate definition of evidence for them.

- (1) two or more well-designed and well-implemented studies employing some combination of relevant rigorous methodologies (e.g., nonrandom quantitative assignment of treatment; longitudinal studies; collection and analysis of relevant qualitative and interview data;

observational; aggregated systematic case studies; cohort comparisons; correlational research with strong statistical controls for selection bias; theory of change analysis) that are of significant duration and with sample sizes sufficient to inform generalizability; and/or

(2) robust, quantifiable findings that a defined practice, strategy or program, or a combination of defined practices, strategies and program have made a significant impact on widely sought publicly reported results that cannot be readily explained, beyond a reasonable doubt, as the result of factors that are unrelated to the practices, strategies and programs under consideration, such as selection bias and other factors that results in non-comparable populations.^{xxxiii}

Whichever sources of evidence are used, the evidence must be judged in the context of a detailed explanation of why the methodology and the study design(s) were the most rigorous and relevant given the intervention and questions under study.

As described above, experimental and quasi-experimental design studies are poor fits for many interventions that could best address the needs of families living with domestic violence. We are enthusiastic about HHS's plans to review its standards of evidence over time in ways that do not compromise rigor, but that do allow for a more complete presentation of evidence. While HHS is limited somewhat by statute, it would be advisable to, whenever possible, include data from other types of trials in assessing fit (the statute essentially describes a minimum condition for evidence—it does not preclude the consideration of evidence that sheds light on generalizability, systems, etc.) In addition to promoting methodological appropriateness (ensuring the right evaluative tools are used is critical to ensuring that the evaluation's verdict is, in fact, accurate), we recommend that evaluations specifically attend to contextual and systemic factors outside the intervention that enhance or impede an effect. As Robert McCall and Beth Green argued, "We are not advocating 'random' research or evaluation;"^{xxxiv} but the intentional application of randomization in situations where it is an appropriate fit and other technologies in other situations.

Since few interventions, if any, have absolute external validity, even within a specific demographic (see discussion above), evidence of effectiveness should include a clear explanation of the populations that benefit most or are most likely to benefit from the interventions under study, and how this was determined. Furthermore, additional weight should be given when study samples are a population reflective of the community's need, rather than a circumscribed population that enables a certain experimental methodology. Populations with multiple challenges should not be excluded from studies unless there is a clear and compelling rationale for excluding these populations beyond validity of data analysis, and that evaluations that make meaningful, rigorous efforts to analyze effect and impact among a diverse realistic sample be given weight for this.

Because the statute aims to scale existing interventions, evidence should also require an explicit exploration and discussion of external contextual and/or systemic factors that must be in place for the intervention to achieve the identified results (e.g., if a home visiting program demonstrating significant

success occurred in the context of a strong and collaborating school system; or if tobacco settlement funding were made available by a state to promote enhanced home visitation and addiction treatment partnerships, giving preference on substance abuse treatment waiting lists to home visitation clients). Because experimental and quasi-experimental designs may, on their own, give insufficient insight into the contextual and/or systemic factors that were prerequisites for a given intervention's effect, an analysis independent of these designs may be required (this is particularly true for factors at the level beyond which the random assignment is possible, but which may be present in decisions about scaling). Identification of contextual factors is ideally informed through existing basic research.

These changes will enable a richer, more innovative and ultimately more impactful pool of program models for states to choose from, and will foster the development of urgently needed models that attend to the complexity of people's lives.

The real world for many women is complex, and further complicated by a fraying social service system. Rigorous, relevant evaluation of interventions that work with them is urgently needed—there are literally lives at stake. We are deeply appreciative of the thoughtfulness of the entire process of putting together the Notice and for the opportunity to submit our comments. We are happy to be of whatever service we can in this endeavor, and encourage HHS to draw upon the talents of researchers and evaluators to support adoption of evidence criteria that encourage, rather than discourage, interventions' meaningfully addressing domestic violence in home visitation programs.

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