



Economic Impact Analysis Virginia Department of Planning and Budget

120 VAC 35-180 – Regulations to Assure the Protection of Participants in Human Research
Department of Behavioral Health and Development Services
August 7, 2009

Summary of the Proposed Amendments to Regulation

The Board of Behavioral Health and Development Services proposes to delete its review responsibilities and more clearly describe those of the department and agency head, to make the regulatory language more person-centered, to change the name of the department, and to eliminate selected provisions of the requirements that are no longer needed.

Result of Analysis

There is insufficient data to accurately compare the magnitude of the benefits versus the costs.

Estimated Economic Impact

The Board of Behavioral Health and Development Services proposes to delete its review responsibilities and more clearly describe those of the department and agency head, to make the regulatory language more person-centered, to change the name of the department¹, and to eliminate selected provisions of the requirements that are no longer needed.

The above proposed changes are not expected to create a significant economic impact as they mainly clarify the language, update new agency name, and clarify the responsibilities. Thus, no significant economic effect is expected as a result of these proposed changes.

However, the proposed changes also include adding a provision barring officials and employees of the agency conducting or authorizing research from acting as a legally authorized representative for an individual participating in the research; changing the section title for

¹ Until July 1, 2009, this agency was known as the Department of Mental Health, Mental Retardation, and Substance Abuse Services. Chapter 813 of the 2009 *Acts of Assembly* changed the name.

“certification process” to “affiliation with a research review committee” and deleting several requirements contained within this section; mandating that in the case of several cooperating institutions, a lead institution be established and that the agreement designating such institution must be in writing; mandating that written reports of suspension or termination due to protocol violations be provided by the chair of the research review committee to the head of the institution; deleting several designated categories of certain kinds of human research activities that involve no more than minimal risk; modifying the section concerning informed consent to clarify what is required when consent is secured orally; changing the records retention requirement from three to six years; removing a requirement that institutions or agencies notify the agency head or the board annually of their compliance with federal policy.

The changes described above may have the potential to create somewhat significant economic impact, but there is no available information from the department to substantiate the extent of their potential impact.

Businesses and Entities Affected

The proposed regulations apply to 40 community service boards, approximately 612 private providers, and 16 state facilities.

Localities Particularly Affected

The proposed regulations apply throughout the Commonwealth.

Projected Impact on Employment

Based on available information, no significant effect on employment is expected.

Effects on the Use and Value of Private Property

Based on available information, no significant effect on the use and value of private property is expected.

Small Businesses: Costs and Other Effects

Most of the 612 private providers are believed to be small businesses. However, based on available information, no significant costs or other economic effects are expected on small businesses.

Small Businesses: Alternative Method that Minimizes Adverse Impact

Based on available information, no significant adverse impact is expected on small businesses.

Real Estate Development Costs

Based on available information, no significant effect on real estate development costs is expected.

Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 36 (06). Section 2.2-4007.H requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, Section 2.2-4007.H requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.