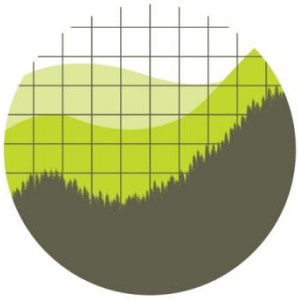

Institute *for*
Policy Integrity
new york university school of law

February 15, 2012

VIA ELECTRONIC COMMUNICATION

Virginia Board of Health
Virginia Department of Health
109 Governor Street
Richmond, Virginia 23219
www.townhall.virginia.gov

RE: Notice of Intended Regulatory Action, Regulations for the Licensure of Abortion Facilities, 12VAC5-412; 28 Va. Reg. Regs. 803 (Jan. 16, 2012)

Dear Commissioner Remley,

The Institute for Policy Integrity (Policy Integrity) at New York University School of Law respectfully submits these comments to the Virginia State Board of Health (the Board) in response to its recent Notice of Intended Regulatory Action (NOIRA) entitled "Regulation for Licensure of Abortion Facilities." Policy Integrity is a nonpartisan think-tank dedicated to improving the quality of government decision-making through advocacy and scholarship in the fields of administrative law, economics, and public policy.

In February 2011, the Virginia General Assembly passed Senate Bill 924, directing the Board to classify "facilities in which 5 or more first trimester abortions per month are performed . . . as a category of 'hospital'" and to promulgate implementing regulations within 280 days from the date of the bill's enactment.[1] In response, the Board used emergency rulemaking procedures to issue temporary regulations that not only reclassified abortion facilities, but also subjected them to a suite of new licensing requirements, inspection procedures, building codes, and other rules.[2] The Board now proposes, through its NOIRA,[3] to develop permanent replacement regulations. Given that the NOIRA was released around the same time as the emergency regulations,[4] it appears that the Board is planning to extend the mandate

[1] 2011 Va. Acts Ch. 670 [hereinafter SB924].

[2] The emergency regulations were approved by the Board on September 15, 2011, and published in the *Virginia Register of Regulations* on January 16, 2012. 12VAC5-410 Regulations for the Licensure of Hospitals in Virginia and 12VAC5-412 Regulations for Licensure of Abortion Facilities, 28 Va. Reg. Regs. 914 (Jan. 16, 2012).

[3] Notice of Intended Regulatory Action, Regulations for the Licensure of Abortion Facilities, 12VAC5-412; 28 Va. Reg. Regs. 803 (Jan. 16, 2012).

[4] *See* Virginia Regulatory Town Hall Form TH-05, "Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document," prepared by the Virginia Department of Health on Sept. 19, 2011 [hereinafter Emergency Background Document], *available at*

of those emergency rules by either adopting their text fully, or at least using them as a basis for developing the permanent regulations.

Virginia law, basic principles of administrative law, and best practices all require the Board to weigh the costs and benefits of its regulatory proposals and examine alternative options. To accomplish this, the Board is required to conduct, to the best of its ability, an empirically grounded analysis of the economic impacts of its proposed rule, and to compare those impacts across all reasonable regulatory alternatives.

The Board's apparent failure to consider any viable regulatory alternatives raises significant concerns. To date, the only substantive explanatory document justifying the draft regulations is a Virginia Regulatory Town Hall Agency Background Document that the Board released in September 2011 as part of its NOIRA and emergency rulemaking process (Emergency Background Document).[5] While the Board asserted in the Emergency Background Document that no alternative regulations exist in light of the Board's mandate under Senate Bill 924,[6] the plain language of that statute does not support such a narrow interpretation. Moreover, such an overly strict reading runs counter to governing state law—including an Executive Order signed by Governor McDonnell in 2010—which requires an alternatives analysis. A more straightforward reading of Senate Bill 924 affords the Board ample discretion to consider a range of alternatives in proposing its permanent regulation, in a manner consistent with the Board's broader mandate to follow prescribed procedures set forth elsewhere in Virginia law. These procedures are designed to ensure the Board engages in well-reasoned, well-supported, and economically justified rulemaking.

Of equal concern is the Board's failure to provide any analytical justifications for the rule in its Emergency Background Document. The document contained no assessment or even acknowledgement of the rule's likely costs and benefits, no citation to supporting evidence and, again, no discussion of viable alternatives. Although identifying and evaluating economic impacts in this area can be difficult and, granted, the Board was working within a tight timeline, it nonetheless should have undertaken a more formal and rigorous accounting of the impacts of the temporary regulations in economic terms. As the Board looks toward enacting a permanent rule, it should not rely upon the cursory and superficial justifications for the emergency rule contained in the Background Document; a much more comprehensive analysis of costs and benefits should be conducted.

These comments first discuss when and how the Board must analyze viable alternatives and economic impacts in weighing regulatory options. They then explain how the preliminary analysis conducted by the Board constituted an irregular deviation from the traditional rulemaking process and suggest how the Board can structure a more sound analysis going forward.

I. State Regulatory Procedure Requires an Economic Impact Analysis and the Evaluation of Regulatory Alternatives

Virginia Administrative Process Act

The Virginia Administrative Process Act (Virginia APA) gives the Department of Planning and Budget

---

http://townhall.virginia.gov/L/GetFile.cfm?File=E:\townhall\docroot\58\3563\6006\AgencyStatement_VDH_6006_v6.pdf.

[5] *Id.*

[6] *Id.* at 7.

(DPB) responsibility for producing an economic impact statement of proposed regulations.[7] The Act requires that before agencies propose a new rule, they submit a copy to the DPB, which then has forty-five days to determine the rule's public benefits and prepare an economic impact analysis, assessing the number of regulated parties and the projected compliance costs, including fiscal impacts to localities.[8] A proper economic impact analysis is, however, predicated on the idea that the agency conducting the rulemaking has considered and is still considering alternatives. For this reason, even before the Board submits its proposed rule to DPB, it must collect information on the likely costs and benefits of its proposal, and how those impacts compare across alternatives.

The Virginia APA further states that if the regulation may have an adverse effect on small businesses, the DPB's economic impact analysis must also detail the compliance costs to small businesses and describe "any less intrusive or less costly alternative methods of achieving the purpose of the regulation."[9]

Public notice for the proposed regulation must contain the agency's justification for the rule, the primary advantages or disadvantages for the public, and the agency's response to the DPB's economic impact analysis.[10] A family impact statement is also required.[11]

Lastly, Article 5 of the Virginia APA sets forth guidelines for judicial review of agency decisions, providing that agency decisions may be reviewed for, among other things, "arbitrariness."[12] Courts may look at various criteria in conducting a review of an agency decision, among them being the failure of an agency to observe required procedure when developing a regulation, as well as the "substantiality of the evidentiary support" for any underlying findings of fact.[13]

Executive Order No. 14

---

[7] Robert W. Hahn, *State and Federal Regulatory Reform: A Comparative Analysis*, 29 J. LEGAL STUD. 873, 908-09 (2000).

[8] VA. CODE ANN. § 2.2-7004.04(A)(1). The "Economic Impact Analysis" provision of the Virginia APA directs that the analysis "shall 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 by the regulation; the projected number of persons and employment positions to be affected; the impact of the regulation on the use and value of private property, including additional costs related to the development of real estate for commercial or residential purposes; and the projected costs to affected businesses, localities, or entities of implementing or complying with the regulations, including the estimated fiscal impact on such localities and sources of potential funds to implement and comply with such regulation." *Id.* at 2.2-4007.04.

[9] *Id.* at §§2.2-4007.04(A)(2). Since the proposed regulations apply to all facilities providing five or more surgical or medication abortions annually, it is probable that small businesses, including doctor's offices, fall within their ambit. *See also id.* at § 2.2-4007.1 (defining a "small business" as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million").

[10] *Id.* at § 2.2-4007.05.

[11] *Id.* at § 2.2-606.

[12] *Id.* at § 2.2-4025.

[13] *Id.* at § 2.2-4027. *See Atkinson v. Virginia Alcoholic Beverage Control Comm'n,* 1Va. App. 172, 336 S.E.2d 527 (1985) (an agency's decision may be subject to reversal because the agency failed to observed required procedures); *Virginia Real Estate Comm'n v. Bias,* 226 Va. 264, 269, 308 S.E.2d 123, 125 (1983) (a reviewing court may reject an agency's decision if the administrative record lacks substantial supporting evidence).

In June 2010, Governor McDonnell issued Executive Order 14 on regulatory review, specifying that agencies' development of regulations must be evidence-based, or supported by the best available information about the impacts of a proposed rule.[14] Agencies must also consider regulatory alternatives in crafting a proposed rule, with the policy ultimately chosen representing the most efficient, most cost-effective, and least intrusive option from among viable alternatives. The relevant text provides:

A. Agencies shall identify the nature and significance of the problem a regulation is intended to address, including, where applicable, why private markets and institutions cannot adequately address the problem.

B. Agencies *shall identify and assess the least costly means including reasonably available alternatives*[15] in lieu of regulation for achieving the goals of a regulation. This shall include where feasible and consistent with public health, safety, and welfare:

    1. The use of economic incentives to encourage the desired outcomes (such as user fees or marketable permits);

    2. The use of information disclosure requirements, rather than regulatory mandates, so that the public can make more informed choices; and

    3. The use of performance standards in place of mandating specific techniques or behavior.

C. Regulatory development shall be based on the *best reasonably available and reliable, scientific, economic, and other information concerning the need for, and consequences of, the intended regulation.* Agencies shall specifically cite the best reasonably available scientific, economic, and other information in support of regulatory proposals.

D. Regulations shall be designed to achieve their intended objective in the most efficient, cost-effective manner.[16]

The DPB is tasked with enforcing compliance with these guiding principles and can start reviewing proposals early, during the NOIRA period. Later, when the rule is ready for proposal, agencies must obtain the attorney general's certification, as well as the DPB's economic analysis and the governor's approval. It bears noting that while the DPB claims to use thorough cost-benefit practices,[17] independent evaluations of the sub-agency—including a survey study conducted by Policy Integrity in 2009—suggest that DPB

[14] Va. Exec. Order No. 14 (2010).

[15] Executive Order 14's requirement that agencies consider viable regulatory alternatives is consistent with the federal regulatory process. Federal agencies have been required to identify and examine "alternative approaches to any given regulatory objective" since 1981, when President Regan issued his own executive order directing agencies to evaluate the economic costs and benefits of proposed rules. Exec. Order No. 12,291 (Feb. 17, 1981). That requirement has been echoed by every subsequent Presidential Executive Order on regulatory review. Exec. Order No. 12,866 (Sept. 30, 1993); Exec. Order. No. 13,563 (Jan. 18, 2011). *See also* Office of Management and Budget, Circular A-4 (Sept. 17, 2003) (requiring the consideration of alternative regulatory approaches). The failure to acknowledge and consider viable alternatives may render an agency's decision reversible by a court under an arbitrary and capricious standard of review. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48-51 (1983).

[16] Va. Exec. Order 14 (2010) (emphasis added).

[17] Jason Schwartz, *52 Experiments with Regulatory Review* 388 (Institute for Policy Integrity, Report No. 6, 2010) (citing to 2009 surveys from a DPB associate director and economic analyst).

currently lacks sufficient resources to consistently meet the statutory requirements for economic analysis.[18] As a result, DPB analyses sometimes fail to account adequately for the costs and benefits of rules or include adequate assessments of regulatory alternatives. In light of this history, the Board should take special care to ensure that an appropriate impact assessment is conducted before the regulations advance further in the regulatory process.

II. The Board Has Failed to Consider Reasonable Regulatory Alternatives

The current administrative record indicates that the Board has thus far failed to adequately identify and consider viable alternatives to the proposed regulations. The template for a Virginia Town Hall Emergency Regulation and NOIRA Agency Background Document contains a section entitled "Alternatives," and under that heading agencies are instructed to "Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider, other alternatives for achieving the need in the most cost-effective manner."[19] In its Emergency Background Document, the Board responded to this instruction with a single-sentence conclusion: "[Senate Bill 924] enacted by the 2011 General Assembly mandates that the Board of Health promulgate these regulations, therefore there are no alternatives to this regulatory action."[20]

This is an overly restrictive interpretation of Senate Bill 924. That bill directs only that "facilities in which 5 or more first trimester abortions per month are performed . . . be classified as a *category* of 'hospital.'"[21] This language seems to grant the Board much more discretion than the Background Document admits. For instance, the Board seems to retain the discretion to classify abortion facilities as a sub-category(ies) of hospital (i.e., "in-patient" or "out-patient"), or to distinguish surgical abortions from medication abortions, or take any number of regulatory approaches. The Board also seems to retain broad authority in deciding what the consequences of the reclassification(s) will be.

The broad scope and technical specificity of the emergency regulations support this reading. The proposed regulations subject abortion facilities to pages of detailed requirements—the "vast majority" of which are new[22]—setting forth how facilities must be licensed and staffed, steps they must take to prevent infection, permissible anesthesia, medical equipment they must have on hand, architectural design standards their buildings must meet, protocols for records storage and disaster preparedness, and so on. The Board cannot have it both ways: the statute gives it no discretion to consider alternatives, while also granting it broad discretion to enact a laundry list of new and highly technical requirements. The notion that Senate Bill 924 precluded the Board from considering a range of alternatives strains basic rules of interpretation. So would the idea that the Senate Bill preempts the need for the Board to analyze the economic impacts of the rule going forward, or the requirement that it articulate the evidence upon which its conclusions were based.

---

[18] *See id.*

[19] Emergency Background Document at 7.

[20] *Id.* The "Emergency Regulations" provision of the Virginia APA, VA. CODE ANN. § 2.2-4011, states that when an agency invokes its emergency rulemaking authority, it must "state in writing the nature of the emergency and of the necessity for such action." VA. CODE ANN. § 2.2-4011(B). While it is clear that the legislature's 280-day mandate required the Board to act quickly, it remains unclear that that deadline excused the Board from having to give any substantive explanation for "the necessity" of its actions.

[21] Senate Bill 924 (*amending* Va. Code Ann. § 32.1-127(B)(1)).

[22] Emergency Background Document at 3.

In considering alternative approaches to the key provisions of the rule, the Board may be able to eliminate some options through a preliminary analysis. Those which remain should be evaluated according to a formal methodology that includes an economic impact assessment, described further below. Among the alternatives that the Board should consider are: different degrees of stringency, different requirements for different sized facilities, performance standards rather than design standards, informational measures rather than regulation, different compliance dates, and different enforcement methods.[23]

III. The Board Has Not Yet Adequately Considered Economic Impacts Nor Relied Upon the Best Available Information

Under Executive Order 14 agencies must "identify and assess the least costly means" of achieving regulatory goals.[24] As such, the Board is required to examine carefully the potential cost implications of transitioning the emergency regulations into permanent regulations, and how those costs compare with other regulatory alternatives. The regulation ultimately proposed should be the result of a methodologically rigorous assessment of expected costs, including direct costs (largely compliance costs) and indirect costs (including the costs associated with restrictions on abortion access). In addition, in order to fulfill its obligations under the Executive Order 14 and comport with best practices, the Board must also carefully and comprehensively analyze the benefits of its proposed rule, and understand the costs in relation to those benefits.

When considering regulation, a responsible regulator must estimate all significant costs and benefits of that regulation. Even for regulation motivated by goals other than economic efficiency, such as the regulation at hand, costs and benefits are a relevant consideration. While measuring and monetizing costs and benefits in this area can be difficult, countless federal and state agencies conduct cost-benefit analyses on a routine basis; these analyses involve looking at the effects on public health that are difficult to quantify and monetize. Even where an agency is unable to monetize all cost and benefits, agencies still recognize those impacts and enumerate them qualitatively.

As noted above, an adequate impact analysis of the emergency regulations currently in place has yet to become part of the administrative record. The lack of analysis conducted during the emergency rulemaking stage suggests that the Board has engaged in, and may be continuing to engage in, an incomplete, cursory, and inadequate rulemaking process. First, nowhere in the record has the Board ever expressly stated the problem the regulations are designed to solve, as required by Executive Order 14. Aside from a blanket assertion that Senate Bill 924 mandates it to promulgate regulations for abortion facilities, the Board offers no explanation of the rationale behind any of its decisions. Second, the Board has failed to identify viable regulatory alternatives. Third, neither the Board nor the DPB have identified and accounted for the benefits of the emergency regulations, including any expected benefits to patient safety. Fourth, neither the Board nor the DPB have ever identified and accounted for the costs of the emergency regulations. Basic observation suggests that serious costs will arise from, *inter alia*, the likelihood that many existing abortion facilities will be unable to meet the new regulatory requirements and have to close their doors, and the resulting decreased availability of medical and surgical abortions.

---

[23] This list is drawn from federal guidelines and is not intended to be exhaustive. *See* Office of Management and Budget, Circular A-4, Sec. D (Sept. 17, 2003); *see also id.* at Sec. E ("Where there is a 'continuum' of alternatives for a standard (such as the level of stringency), [agencies] generally should analyze at least three options: the preferred option; a more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and a less stringent option that costs less (and presumably generates fewer benefits) than the preferred option.").

[24] Va. Exec. Order 14 (2010).

The absence of such analysis falls below a reasonable standard of an appropriate impact assessment. As the Board moves forward in promulgating permanent rules, it is obligated to undertake a more formal accounting of the impacts of the proposed regulations in economic terms.

Failure to Provide Evidence of the Existence of a Regulatory Problem

At the outset, the proposed regulations fail to accurately identify or quantify the harm that they are intended to relieve. The Emergency Background Document simply states that Senate Bill 924 "mandates" these regulations. As noted above, this interpretation is overly strict and conflicts with the Board's legal requirements under the Virginia APA and Executive Order 14 to consider regulatory alternatives. The proposed rule does not state nor provide any reasonable basis or evidence for a belief that the rule, as currently structured, is necessary to address a legitimate problem. According to State Senator Ryan McDougle, the legislative sponsor of Senate Bill 924, the bill was intended to "to make sure that all medical procedures are done in a safe manner."[25] As the Board moves forward in the formal rulemaking process, it can seek to achieve this purpose in a cost-effective manner based on evidence about whether and to what extent abortion facilities' current practices pose unnecessary dangers to patients. This information can be obtained by a number of means, including statistical evidence, samplings of populations, or administration of self-report surveys to health care works. With this information, evidence-based regulations can be put in place to define abortion providers within a category of hospitals subject to regulatory requirements that are appropriate for them.

Failure to Consider Costs and Benefits

No analysis of the costs or benefits of the regulations has been offered by the Board or the DPB. When the requisite impact analysis is conducted, the analysts must be sure to proffer the scientific, statistical, or empirical support they relied upon in considering costs and benefits. Such information will specify how many facilities and how many individuals—prospective patients as well as facility employees—are expected to be affected by the key regulatory provisions.

For instance, the following cost questions, among others, must be addressed:

- How many abortion facilities would currently *not* meet the new building design standards being prescribed?
- How expensive will compliance with those standards be, and will facilities be able to afford it?
- How many women would not obtain an abortion or be forced to incur additional expenses to obtain one, should the abortion facility nearest to their home close temporarily or lose its license on account of failing to comply with a new regulatory requirement?
- What are the costs associated with the diminished access to abortion providers experienced by these women?
- What costs may diminished access impose on other healthcare facilities?

The following benefit questions, among others, must be addressed:

- How many surgical abortion patients will benefit from the imposition of the rule's new physical plant standards? How many medication abortion patients?

[25] Prue Salasky, "'Emergency Regulations' Threaten Virginia's Abortion Clinics" (Sept. 13, 2011), http://articles.dailypress.com/2011-09-13/health/dp-nws-abortion-va-0910-20110913_1_abortion-clinics-first-trimester-abortions-abortion-services.

- How many patients will benefit from the rules that require abortion facilities to procure and maintain various medical equipment? How large will these benefits be?
- Which of these regulations will increase patient safety, and by how much? Might it decrease it?

This empirical information is easily ascertainable. The Board or DPB could collect statistics from the regulated facilities, advocacy groups, or state agencies. The Board or DPB could also perform statistical sampling of populations, administer anonymous self-report surveys to patient communities or healthcare providers, or hire outside consultants to undertake this endeavor, as has been done on numerous occasions by state and federal agencies when conducting impact analysis.

In assessing economic impacts, the Board should also examine how the proposed regulations will affect subgroups of the population, or how the costs and benefits are distributed amongst subpopulations.[26] For instance, rural women, low-income women, and women of color might be disproportionately affected by the regulations, especially if existing abortion facilities close or lose their license on account of failing to comply with new requirements.

Failure to Cite Supporting Information

Executive Order 14 requires agencies to base their decisions on the "best reasonably available and reliable, scientific, economic, and other information concerning the need for, and consequences of, the intended regulation."[27] The failure to rely upon supporting evidence could render a decision "arbitrary" under the Virginia APA.[28] Yet as it stands, there is a dearth of supporting information in the administrative record. Going forward, the Board must compile medical studies and other research pertaining to the need for key provisions of the proposed regulations and their expected consequences relative to the current regulatory scheme. While such evidence is required for all key attributes of the proposed rule, it will carry particular weight in justifying particular provisions—those which, at first glance, appear to impose compliance costs and other costs far in excess of any safety benefits. For instance, draft regulation 12 VAC 5-412-130 allows the Department of Health to revoke an abortion facility's license if the Department determines that the facility is in violation "of any applicable regulation," however minor or unrelated to patient care. It is certain that an alternative, more benefit-cost justified policy exists; perhaps the optimal approach would require a "significant" violation or include a reference to patients' "immediate" safety. The same is probably true of draft provision 12 VAC 5-412-380, which appears to require all existing abortion facilities to come into compliance with new building codes and standards within the next two years.[29]

Analysis of Family Impacts

In addition to economic impacts, Virginia law requires that all state agencies and boards situated within the executive branch consider the likely impacts of a proposed policy or regulation "on family formation,

---

[26] The assessment of distributional impacts is a crucial component of rulemaking best practices. *See* Exec. Order 13,563 (Jan. 18, 2011); Office of Management and Budget, Circular A-4, Section D (Sept. 17, 2003).

[27] Va. Exec. Order 14 (2010).

[28] VA. CODE ANN. § 2.2-4025.

[29] These codes and standards are to be found in the *2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute.* 12 VAC-412-380, 28 Va. Reg. Regs. 10, 925 (Jan. 15, 2012). By their own terms, however, these guidelines were intended to apply only to *new* health care facilities, not existing structures—a fact that casts additional doubt on the economic justifiability of this particular provision of the proposed rule. Facility Guidelines Institute, *Guidelines for Design and Construction of Health Care Facilities* 4 (2010).

stability, and autonomy."[30] The template for agency background documents solicits this information for public review by asking agencies to explain the extent to which a proposed regulation will, *inter alia*, "encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents;" or "strengthen or erode the marital commitment;" or "increase or decrease disposable family income."[31]

As an administrative practice, it is unclear what, if any, advantage is gained by requiring this type of family impact statement. Nonetheless, insofar as the Board is legally required to prepare the statement as part of its justification for any proposed regulations, the statement should adhere to the same principles that undergird economic impact statements: it should be well-reasoned and supported by citations to empirical information. The statement provided by the Board in its Emergency Background Document does not meet this standard, as there the Board merely offered the following perfunctory conclusion: "The proposed regulatory action will not have any impact on the institution of the family and family stability."[32] Especially given the nature of the regulation, this conclusion is unsupported.

Conclusion

The fact that Senate Bill 924 called upon the Board to issue new regulations pertaining to abortion facilities does not obviate the Board's obligation to adequately justify the specific regulations it seeks to promulgate. Thus far, the Board has failed to provide any substantive justifications for its emergency regulations. During the emergency stage of the rulemaking process, the Board never articulated an existent problem, nor considered reasonable alternatives, nor provided an accurate, realistic, and evidence-based assessment of the potential effects of the rule. Going forward, the Board must consider—with the assistance of the DPB—an accurate and substantive accounting of the rule's potential costs and benefits, particularly those related to public health. The cursory and superficial analysis contained in the Emergency Background Document will be insufficient.

As the Board seeks to replace its emergency regulations with permanent ones, a failure to correct the deficiencies described above will violate best practices, as well as Executive Order 14. It may also render the regulations "arbitrary" under Article 5 of the Virginia Administrative Process Act.

[30] VA. CODE ANN. § 2.2-606.

[31] Emergency Background Document at 8-9.

[32] *Id.*