

New Directions in Regulatory Reform: Prospects for Reducing Regulatory Burden Through Risk-Informed Approaches in Federal Law Governing American Higher Education

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I. INTRODUCTION AND OVERVIEW

The beginning of the 21st century has brought unprecedented change to the higher education community. The last decade has produced significant increases in enrolled students, financial aid demands, numbers and variety of institutions, types of educational delivery methods, and employer expectations, to name a few. Technological developments are driving the pace of change on many fronts even more rapidly—a pace will likely increase in the years to come.

Meanwhile, regulatory systems are not keeping up. Decades of statutory and regulatory amendments have created a dense, labyrinthine thicket of rules and requirements that reflect competing priorities and changing compliance standards. Too much of the federal regulatory system relies on a one-size-fits-all reporting and enforcement regime that is out of sync with the broad diversity among American institutions of higher education and numerous interests and needs of students. As a consequence, the system too often fails to direct limited oversight and enforcement resources in the most effective, efficient manner. Without question, we need new regulatory strategies that can respond to these shifts and, as important, can prepare for the new changes on the horizon.

“Risk-informed” regulatory regimes have significant promise to correct some of the problems of the past and help prepare the system for today and tomorrow. These regimes present a fundamental shift in the regulatory paradigm. Instead of requiring the institution to comply with every requirement and regulation, institutions are required to comply with some baseline rules and submit to a preliminary risk assessment. When that assessment reveals a problem, regulators and/or their non-governmental partners may take additional action that ranges from requiring more information or participation in technical assistance programs, mandating corrective action, or – in worst case scenarios—applying sanctions.¹ Risk-informed regimes reflect a hybrid of “deterministic” (one size fits all) and “risk-based” systems (regulatory action *only* applies when a regulated entity presents a certain level of risk, so some entities are not regulated at all).

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When that assessment reveals a problem, regulators may take additional action that ranges from requiring more information or participation in technical assistance programs, mandating corrective action, or – in worst case scenarios – applying sanctions

Incorporating risk assessment into regulatory regimes has been endorsed by leading higher education organizations² and by both sides of the political aisle.³ Supporting organizations recognize the prospective efficiency, as

¹ See Jonathan Coburn and Greg Weddle, Risk-Based Regulation: Learning from the Experience of Others, BioProcess Int'l 22-23 (Sept. 2006).

² See, e.g., Association of American Universities, AAU Submits Comments on Draft HEA Bill to Senator Harkin (Aug. 26, 2014), <http://www.aau.edu/policy/article.aspx?id=15447>; Peter McPherson, Association of Public and Land-grant Universities, APLU Comments on HEAA Discussion Draft (Aug. 22, 2014), available at: https://www.insidehighered.com/sites/default/server_files/files/APLU%20HEAA%20Response%20Final%20082214.pdf; Molly Corbett Broad, American Council on Education, Recommendations from 39 Higher Education Associations for the Reauthorization of the Higher Education Act (Aug. 2, 2013), <http://www.acenet.edu/news-room/Documents/HEA-Reauthorization-Recs-080213.pdf>.

³ For instance, a bipartisan group of Senators endorsed the concept behind the Food and Drug Administration's proposed risk-based approach to the regulation of medical devices, while the group also emphasized the importance of transparency in communicating to stakeholders to avoid confusion. Sens. Michael Bennet, Orrin Hatch, Tom Harkin, Lamar Alexander, Mark Warner, and Richard Burr, Letter to Commissioner Hamburg (March 18, 2014) (“Given that a large number of medical mobile applications could be actively regulated under the statute using this definition, we appreciate the FDA's decision to use a risk-based approach to regulation.”), <http://www.help.senate.gov/newsroom/press/release/?id=2354f485-f387-40c4-80c9-158491f2fd1a>; see also discussion drafts of HEA reauthorization and the America COMPETES Act, *infra* notes 34-35.

well as better deployment of resources that risk-informed regimes can promote. Most proposals, however, only include a brief reference to the concept without fully exploring the analytical foundations for successful adoption and implementation of risk-informed systems—or even clear and comprehensive definitions that precisely define the term.

This paper is intended to fill that void. It provides a vision and framework for prospective risk-informed federal regulatory reform affecting American higher education to create more effective and streamlined oversight and action aligned with the goals of the Higher Education Act (HEA). It is intended to inform and illustrate how risk-informed approaches could work in the regulation of postsecondary education as a foundation for further dialogue regarding specific recommendations that should be considered in the context of the reauthorization of the HEA.⁴ Within the paper:

- Section II provides an overview of the relevant policy landscape that should inform any evaluation of prospective risk-informed regulatory regimes in American higher education. It then provides a definition of risk-informed regulation, elaborating on differences from other regulatory approaches and key elements integral to the successful development of such a regime.
- Section III provides domestic and international illustrations of the incorporation of risk into various regulatory settings.
- Section IV distills key design, implementation, and evaluation principles derived from risk-informed experiences in other sectors and settings. It also provides a beginning list of sample policy areas where risk-informed reform might be undertaken in higher education.
- Section V concludes the paper with recommendations and key questions for policymakers to consider.

The paper also includes two appendices: a prospective “process map” to inform future policy deliberations and a recommended reading list.



To design and implement risk-informed regimes successfully, policymakers, advocates, and practitioners—working together—must be willing to think creatively and to return to first principles for federal regulation (maintaining provisions for strong enforcement when needed). Some existing regulatory provisions will need to make way for more efficient and effective regulatory regimes that can meet the challenges of today and tomorrow. (Meaningful regulation that ensures effective, impactful investment of federal funding in higher education should, of course, be preserved.) In addition, risk-informed regimes may be established in ways that align with performance-based regimes, which are currently the subject of significant exploration and pursuit among various higher education sectors and institutions.⁵

This paper focuses on identifying the models, conditions, and areas for exploration to guide future deliberations

⁴ This paper was developed with the support of Lumina Foundation at the request of the American Council on Education as part of its work with the Task Force on Government Regulation of Higher Education, made up of 16 higher education leaders appointed by a bipartisan group of U.S. Senators. It is intended to serve as a resource for the Task Force and to complement its Final Report. In keeping with the Task Force’s scope, the paper primarily focuses on the U.S. Department of Education’s regulatory regimes under the HEA, but the principles and concepts within the paper may be applied in a variety of other contexts that affect institutions of higher education, such as requirements related to research grants funded by other federal agencies.

⁵ Although beyond the scope of this paper, the prospective alignment of federally-embedded risk-informed regimes in higher education with performance-based, outcome-centered policies merits further attention – particularly in the context of the much-anticipated reauthorization of the Higher Education Act. See Arthur L. Coleman, Bethany M. Little, Teresa E. Taylor, and Katherine E. Lipper, *Getting Our House in Order* (publication forthcoming in winter 2015).

among policymakers and stakeholders in the higher education community. It does *not* propose that risk-informed regimes are a panacea for all regulatory woes. As with any regulatory regime, there are strengths and challenges to successful design, implementation, and evaluation. Those should be fully understood.

Correspondingly, the paper does *not* present an argument for an immediate and complete overhaul of the entire federal regulatory system to incorporate risk-informed regimes. The graphic below illustrates one way of clustering the major areas of federal compliance for higher education institutions. Only some of these are likely both appropriate and ripe for the incorporation of risk-informed regimes. In some cases, risk-informed systems will never be appropriate. Civil rights enforcement, for example, is based on constitutionally-guaranteed individual student rights—parameters that likely cannot and should not be adjusted based on the level of risk involved. In other cases, data sources and systems are not yet mature enough to support the development of accurate, meaningful risk assessments.



The paper strongly counsels that well-informed deliberation takes place before any risk-informed regime is adopted and implemented. The problems in today’s regulatory environment for higher education institutions built up over decades; they will not be solved in a month—or a year. We hope that this paper, however, can serve as a foundation and resource for policymakers and stakeholders in higher education as risk-informed regimes are considered, designed, implemented, and evaluated.

II. THE RELEVANT EDUCATION LANDSCAPE AND POTENTIAL FOR RISK-INFORMED REGULATION

A. The Regulatory and Policy Landscape

American higher education is provided by a vibrant array of colleges, universities, and other providers. More than 7,000 institutions of higher education operate today—an increase of more than 500 in the past decade.⁶ In addition to growth in the sector, many institutions are expanding internally, creating new programs that leverage technology and can respond to the needs of students in a new way, such as competency-based learning models, distance learning opportunities, and prior learning assessments.

The population of students has grown, too, as postsecondary credentials have become increasingly important for sustainable employment. In the fall of 2012, there were 17.7 million undergraduate students and 2.9 million graduate students attending degree-granting IHEs in the U.S. —an almost threefold increase from the 5.9 million students enrolled in postsecondary programs when the HEA was originally passed in 1965.⁷ This growth can be

⁶ Nat’l Ctr. for Educ. Statistics, Fast Facts: Educational Institutions, <http://nces.ed.gov/fastfacts/display.asp?id=84> (last accessed Oct. 26, 2014).

⁷ IPEDS, Condition of Education Report (updated May 2014), http://nces.ed.gov/programs/coe/indicator_csb.asp; Thomas D. Snyder and Sally A. Dillow, Inst. of Educ. Scis, Nat’l Ctr for Educ. Statistics, Digest of Education Statistics 2012 319, t.221 (NCES 2014-015) (2013). The pace of growth has been particularly brisk recently: enrollment at degree-granting institutions increased 32 percent between 2001 and 2011, from 15.9 million to 21 million. Id. at 307. And USED expects overall postsecondary enrollments to increase by 14 percent from 2011 to 2022. U.S. Dep’t of Educ., Projections of Education Statistics to 2022, NCES 2014-051, 19 (Feb. 2014), <http://nces.ed.gov/pubs2014/2014051.pdf>.

largely attributed to the fact that, in most of today's economy, postsecondary credentials are a pre-requisite to job security and long-term financial health. The pay gap between college graduates and non-college graduates reached a record high in 2013, as those with four-year degrees made 98 percent more an hour on average than people without one.⁸

The federal regulatory regime has also significantly grown and evolved since HEA's original passage—with both Congress and the U.S. Department of Education (ED) adding layers of complexity (and significant burdens) along the way. In exercising its regulatory oversight functions, ED tends to evaluate nearly all institutions in the same way. But consequential institutional differences should be taken into account in regulatory responses, even if systems are framed around common interests and metrics.

Enforcement tools tend to address deficits with blunt, one-size enforcement mechanisms, which can result in less targeted, timely, and effective action. The loss of Title IV eligibility, in particular, would have an enormous impact on students enrolled at an institution, and ED is often justifiably hesitant to use this enforcement tool. But that means that ED might only act in the most egregious cases, and not have the intermediate processes in place to take action that could help mitigate the impact of an identified problem.

Moreover, the regulatory landscape shifts frequently, creating an unstable environment that makes it more difficult for institutions and non-governmental partners to carry out their responsibilities under federal law.

Despite capacity challenges and other limitations, the federal government's influence and involvement in higher education will not abate anytime soon as long as today's high demand for federal financial aid continues.

The challenge will be how to prioritize and direct federal attention to those areas that merit the most significant oversight. Incorporating risk assessments have significant potential to do just that.

This uncertainty is pervasive and contributes to unnecessarily high costs and ineffective deployment of limited resources. In 2012 alone, through electronic announcements and Dear Colleague letters, ED issued at least 270 regulatory updates or modifications – more than one change per workday.⁹ At the same time, though Congress has provided ED with various oversight tools (including the authority to close a school immediately), ED uses these tools irregularly and idiosyncratically. In 2013, for example, the Department announced it would levy fines on institutions for alleged violations that occurred in 1995—so nearly two decades passed between the violation and ED's levying of fines.¹⁰

This complex, unsettled terrain has a significant impact on institutions and their ability to fulfill their primary missions of educating. Regulatory compliance burdens detract from their ability to focus more resources on academic programs and services that directly benefit students. Calculating the cost of federal regulatory com-

⁸ This represents an increase from 89 percent five years earlier, 85 percent a decade earlier, and 64 percent in the early 1980s. David Leonhardt, Is College Worth It? Clearly, New Data Say, N.Y. Times (May 27, 2014), <http://mobile.nytimes.com/2014/05/27/upshot/is-college-worth-it-clearly-new-data-say.html>; see also U.S. Departments of Education and Treasury, The Economics of Higher Education 3 (Dec. 2012), http://www.treasury.gov/connect/blog/Documents/20121212_Economics%20of%20Higher%20Ed_vFINAL.pdf (“The median weekly earnings of a full-time, bachelor’s degree holder in 2011 were 64 percent higher than those of a high school graduate (\$1,053 compared to \$638). The earnings differential grew steadily throughout the 1980s and 1990s.”)

⁹ The gainful employment regulations alone spawned 43 separate Dear Colleague letters and electronic announcements further detailing institutional reporting and disclosure requirements. Broad, supra note 2, at 20.

¹⁰ Id. at 16.

pliance is challenging—largely because requirements implicate a wide range of administrative staff, institutional leaders, and faculty members – but a few data points exist. A study of financial aid officers found that about two thirds reported that their financial aid office was facing a moderate or severe resource shortage that affected their ability to provide adequate personnel for administering Title IV programs and to provide adequate financial aid counseling for students.¹¹ Eighty percent of respondents identified greater regulatory / compliance workload as a “major” factor behind the shortage.¹² Hartwick College, a liberal arts college in New York, determined in 2012 that it spent about seven percent of its operating budget (nearly \$300,000) annually on federal compliance related activities.¹³ Similar studies have been launched at other institutions recently, including at Vanderbilt University.

It is important to recognize that ED is the smallest of Cabinet-level federal agencies, with limited staff resources. Though the federal aid programs have grown six fold since the early 1980s, ED only employs 0.1 percent of the total Executive Branch workforce, with the number of ED employees quite close to its levels in the late 1970s, before it was a Cabinet-level agency.¹⁴ Its partners in oversight and accountability—states and recognized accrediting agencies—also have significant capacity challenges. Regulatory breadth strains the system and ED lacks the capacity and expertise to do everything well and in a timely manner. And ED’s efforts to delegate additional responsibilities to accrediting agencies has created new burdens that accrediting agencies are not always experienced or equipped to enforce. But the reality is that, despite these capacity challenges and other limitations, the federal government’s influence and involvement in higher education will not abate anytime soon as long as today’s high demand for federal financial aid continues. The challenge will be how to prioritize and direct federal attention to those areas that merit the most significant oversight. Incorporating risk assessments have significant potential to do just that.

¹¹ Nat’l Ass’n of Student Financial Aid Administrators, Findings from the 2010 NASFAA Administrative Burden Survey (2011), <http://www.nasfaa.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=3903>.

¹² Id.

¹³ This represents \$192,874 in salary costs, \$30,900 in direct costs, and \$11,515 accreditation costs. Kelly Zack-Decker, Compliance at Hartwick College: A Special Report to the President of the College 4 (Dec. 2012), available at: http://www.naicu.edu/docLib/20130315_Compliance-HartwickColl-12-12.pdf.

¹⁴ USED currently has approximately 4,200 employees, compared with 3,000 in 1979—far fewer than the 17,000 projected in 1980 when President Carter elevated USED to a Cabinet-level agency. White House, The Executive Branch, <http://www.whitehouse.gov/our-government/executive-branch> (last accessed Nov. 3, 2014); U.S. Dep’t of Educ., An Overview of the U.S. Department of Education (Sept. 2010), http://www2.ed.gov/about/overview/focus/what_pg2.html; United Press International, Education Department Created, The Palm Beach Post (Oct. 18, 1979), available at: <http://news.google.com/newspapers?id=0sZUAAAIAIBAJ&sjid=ejsNAAAAIAIBAJ&pg=1984,3959160&dq=department+of+education&hl=en>.

B. An Overview of Risk-Informed Regulation

1. *The Risk-Informed Concept*

Risk-informed systems are best understood as part of a spectrum of regulatory approaches that ranges from subjecting all regulated entities to highly prescriptive requirements to only requiring entities deemed risky to regulatory oversight.¹⁵ This paper's recommended risk-informed approach is in the middle of this spectrum, as illustrated below. It is also important not to confuse a risk-informed system with a crisis management system, as the former focuses on prioritizing and managing risks while the latter concerns procedures that will be activated when a particular risk comes to fruition.

The more traditional or "deterministic" system uses the same rules and consequences for all regulated entities, regardless of the level of risk they pose. Most federal requirements related to accreditation of institutions of higher education qualify as deterministic. Historically, for instance, in order to grant accreditation status to institutions as a pre-requisite for participation in federal financial aid programs, accrediting agencies must have been recognized by ED, as advised by the National Advisory Committee on Institutional Quality and Integrity (NACIQI). Because an accrediting agency is either recognized or not recognized, all agencies seeking recognition have been required to submit the same documentation for the same level of review.

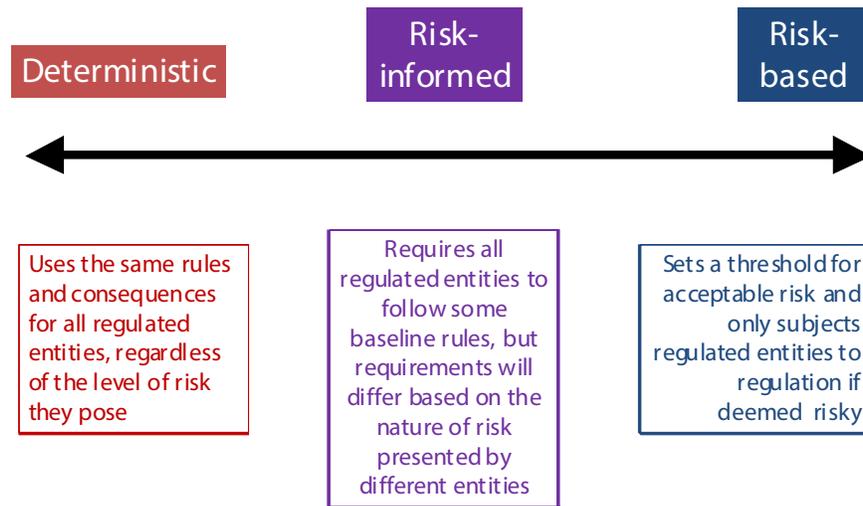
A fully risk-based system sets a threshold for acceptable risk and only subjects regulated groups to regulation if the regulatory body deems them risky. As a result, regulated entities deemed not risky can completely bypass oversight and enforcement. For example, all agencies in the federal government have used common audit standards that classify federal programs as "major" or "non major" (measured by the level of federal funding for the overall program and for the specific recipient) and then determine whether recipients qualify as "low risk" or "high risk."¹⁶ If a recipient is granted low-risk status, it is exempted from several federal audit requirements for as long as it undergoes no major changes.¹⁷ These rules allow auditors to avoid performing time consuming risk assessments for relatively small federal programs, focus their attention on those programs most likely to present problems, and relieve those with strong performance records of some regulatory burdens.

¹⁵ These ideas were drawn from a number of scholarly works, particularly Coburn and Weddle, *supra* note 1; Julia Black and Robert Baldwin, Really Responsive Risk-Based Regulation, 32 L.& Pol'y 181, 184-85 (2010); and Peter May, Performance-Based Regulation, Jerusalem Papers in Regulation & Governance Working Paper No. 2 (April 2010), <http://regulation.huji.ac.il/papers/jp2.pdf>.

¹⁶ Auditors make a holistic determination of risk using factors including current and prior audit results (e.g., evidence of weak or multiple internal controls and prior audit findings indicates higher risk); results from oversight and monitoring by relevant federal agencies (e.g., monitoring that identified significant programs indicates higher risk; and the inherent risk of the program (e.g., greater program complexity or new programs indicates higher risk). OMB Super Circular §§200.518-520, 78 Fed. Reg. 78590, 78670-72 (Dec. 26, 2013), <http://www.gpo.gov/fdsys/pkg/FR-2013-12-26/pdf/2013-30465.pdf>.

¹⁷ Low-risk entities are only obligated to be audited for the following programs: (1) All major programs not identified as low risk; (2) all non-major programs identified as high risk; and (3) any additional programs to fulfill "percentage of coverage" rules. On the third group of programs, federal auditors are generally required to audit major programs that make up at least 40 percent of the total federal awards expended on the entity. If major programs do not comprise at least 40 percent, the auditor must select additional programs (either major or non-major) to include in the audit. For low risk auditees, the percentage is dropped to 20 percent, meaning that it is less likely that the auditor is required to include additional programs in the audit to fulfill the percentage of coverage rule. *Id.* at §200.518(f); see also Am. Inst. of CPAs, OMB Circular A-133 Audit Refresher –Major Programs (2008), <http://www.aicpa.org/interestareas/governmentalauditquality/resources/ombcirculara133/ombcirculara-133auditrefresher-majorprograms/pages/default.aspx>.

Understanding the Risk-Related Regulatory Design Spectrum



A risk-informed system adopts a hybrid approach, combining risk-based enforcement mechanisms with baseline deterministic regulatory rules. All regulated groups must follow those baseline rules and submit to a preliminary risk assessment, but the regulatory response will differ based on the degree of risk presented by different groups. Systems vary, but risk-informed systems commonly involve targeting enforcement resources on the basis of assessment of risk that a regulated entity poses to the regulator’s objectives—which may be paired with additional requirements for supplying information on those entities that pose greater risks. Several examples of this approach are provided in Section III.

To illustrate differences between these regimes, imagine an obstacle course that a set of Army recruits must complete to be eligible for active duty. The “risk” here would be that recruits would fail to perform in active duty, putting themselves and their fellow soldiers in danger. A traditional regulatory or deterministic system would require all recruits to complete the obstacle course regardless of past performance or ability. On the other end of the spectrum, a risk-based system would require only those recruits with certain risk factors to complete the obstacle course, such as failure to complete prior physical tests, existing health conditions, or other indicators that they may be less able to serve effectively as an active soldier. Between the two extremes, risk-informed system would require all recruits to pass through a portion of the obstacle course, but require only those recruits with identified risk factors to complete a second portion. (This portion would be optimally designed to test different levels of risk for different recruits, such as an extra climbing exercise for recruits with a fear of heights, an extra weight lifting exercise for recruits with less demonstrated strength, or an extra leadership exercise for recruits who did not participate sufficiently in prior group activities.)

Extending this illustration to a higher education setting, a risk-informed system might require all institutions to overcome a baseline “obstacle” of key reporting and data collection requirements, as well as a confirmation of accreditation status and state authorization. For those institutions with indicators of risks of financial instability, additional assurances may be appropriate to ensure that the institution’s financial health is sufficient to support its students. (Indeed, ED already has a requirement similar to this.) For institutions with a low graduation rate, additional information on transfer rates may help to overcome concerns about the institution’s graduation rate.

2. Core Functions Within Risk-Informed Regimes

Determining whether to pursue the development of a risk-informed regime requires comprehensive understanding of the primary functions in these systems.¹⁸ A review of the frameworks behind risk-informed regimes in several countries found that, despite significant variation in the details, five functions are common:¹⁹

1. *Defining the purpose and goals of the system in terms of specific risks.* It is important to distinguish overarching, big picture risks from the specific, measurable risks that go into a risk-assessment. Some risk will always be present within the system, and this step should focus on defining the precise risk that the regulatory regime seeks to assess and avoid. For example, ED's financial responsibility requirements for institutions (described in detail on page 24) are intended to assess the specific risk of imminent closure—not a general examination of whether an institution is financially responsible.
2. *Determining the responsible agency or organization's own risk appetite.* This step has proved to be “extremely challenging” for regulators and their non-governmental partners responsible for risk-informed regimes.²⁰ Political risks—including reactions from politicians, the media, stakeholders, and the general public—are always present, and may be particularly strong in the design and early implementation stages.
3. *Assessing the risk and its likelihood of occurrence.* Two broad categories of risk are usually involved in a risk assessment: (1) risks inherent to activity within the sector; and (2) individual entities' efforts to manage and control those risks.²¹ Though they can be combined in different ways, inherent risks and management/control risks work together to provide a complete picture of the risks posed by an individual entity. Metrics for these risks should center on what really matters within the regime—and what is most appropriate for the responsible agency or regulatory partner. Some regimes are highly quantitative (e.g., financial responsibility ratios) while others may be more qualitative and, therefore, rely more on the informed professional judgment of those performing the risk assessment (e.g., accreditation).²²
4. *Assigning scores or ratings to regulated entities on the basis of risk assessments.* Many systems use relatively simple “red,” “yellow,” and “green” categories to differentiate different levels of risk (one example of this is given on the next page). Others have a more granular system with many categories; the Financial Services Authority in the United Kingdom, for example, has 15 different categories.²³ Ideally, data and information necessary for risk assessments can be acquired through existing mechanisms to avoid new compliance burdens.
5. *Linking regulatory responses and resources to scores or ratings categories (for individual regulated entities and/or for system-wide issues).* Regulatory responses should be targeted at providing support to address identified problems and imposing more significant consequences for egregious or repeat violations. Generally, requirements should be loosened when low risk is presented and should be tightened when medium or high risk is presented.

Additionally, ongoing monitoring and evaluation of the system and its effects is essential, with particular focus in early years to allow for fine-tuning.

¹⁸ These functions presuppose that an appropriate issue or program area for risk-informed regulation has been identified. Not all areas of a system will be optimal candidates for a risk-informed regime. Implementation should only take place in areas where appropriate foundations are present (e.g., legal authority, sufficient data systems, and stakeholder support).

¹⁹ Black and Baldwin, *supra* note 15, at 184-85.

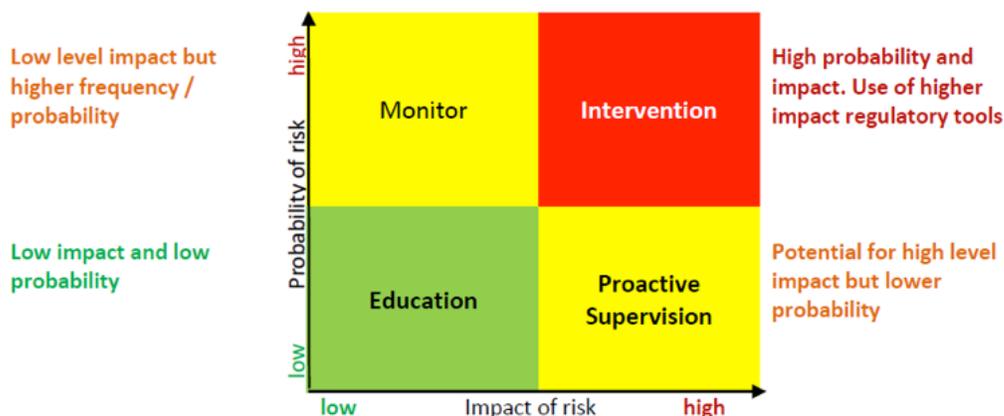
²⁰ *Id.* at 184.

²¹ *Id.*

²² *Id.* at 185.

²³ *Id.*

Fully developed risk-informed systems are usually graphically depicted to illustrate how risk and regulatory response relate under different conditions. The Financial Services Commission of Ontario (FSCO) developed the graphic on the next page to show how impact and probability guide risk assessments and regulatory responses.²⁴



The FSCO defines “green” entities as those that present low probability *and* low impact risk. This group is required to support that determination, but—once that determination is made—need not do more. In such cases, FSCO only provides general updates and communications; no specific plan to engage individual entities within this category exists. For “yellow” entities that present low probability but high impact of risk, FSCO proactively supervises through ongoing monitoring, regular reporting, and possibly site visits. For the other “yellow” entities that present high probability but low impact risk, FSCO will monitor with less rigor than the low probability / high impact group (given that the impact of risk is lower), but will regularly monitor and engage on specific issues identified. “Red” entities present high probability and high impact risk. Because these entities present such a significant danger, they require the most FSCO time and effort through regular interactions, proactive measures to mitigate risks, site visits, and—in egregious cases—enforcement actions.

The regulation of scientific laboratories provides a useful illustration of these concepts.²⁵ A laboratory with “high impact” risk involves experiments with highly hazardous materials such as plutonium or uranium. In those cases, the danger to the public is high enough to merit proactive regulatory supervision, even if the laboratory only has a handful of researchers. A laboratory with “high probability” risk might involve many researchers working on many experiments. These projects may not involve highly hazardous materials (so the impact of the risk is low), but the frequency and number of experiments increases the probability of something going wrong. In those cases, regulatory monitoring is appropriate to keep an eye on potential problems. When both risk conditions are present—highly hazardous materials with a large number of experiments and researchers involved—regulators and their non-governmental partners may need to intervene with stronger regulatory tools to protect public safety. But when neither risk condition is present—no highly hazardous materials and a smaller number of experiments and researchers involved—regulators likely only need to ensure that those laboratories receive appropriate education about regulatory changes and other key developments.

These concepts can also be applied to higher education. One example might involve assessing the risk of students

²⁴ Financial Services Commission of Ontario, Risk-Based Regulation: Framework Document 4 (2011), http://www.fSCO.gov.on.ca/en/pensions/fSCO_consultations/Documents/Framework_Final.pdf.

²⁵ The principles undergirding this simple illustration are reflected more robustly in several federal statutes, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act (which governs the safe generation, storage, transport, and disposal of hazardous chemical waste), and the Clean Air Act and Federal Water Pollution Control Act. See The Nat’l Acads Press, *Prudent Practices in the Laboratory: Handling and Disposal of Chemicals* 198 (1995).

at an institution eventually defaulting on their loans. At a very basic level, those colleges and universities with a large number of students taking out loans would have a higher probability of default, while those with very high tuition or very high borrowing amounts would have a higher impact of default because repayment would be a more significant financial burden. (Additional risk indicators could be built into a system, but these indicators are provided simply for illustrative purposes.) Regulatory responses by ED and its partners could be designed to focus most on those institutions with both risk conditions present, while designing supportive monitoring and supervision efforts for those institutions with one of the risk conditions present.

3. Benefits and Costs

When considering the plausibility of pursuing a risk-informed regime, the potential benefits and challenges inherent to that model should be fully understood.²⁶ Fundamentally, the approach provides an opportunity to realign regulatory requirements with the primary risks that rules and regulations are intended to prevent. Correspondingly, these regimes allow regulators and their non-governmental partners to acknowledge differences among regulated entities and to develop more systematic responses to the variety of unique circumstances presented within a regulatory area.

At the same time, however, these regimes require significant investment in the design process, particularly in identifying appropriate metrics and thresholds. Though most stakeholders are likely to embrace risk-informed regulation conceptually, that support can evaporate when the work of setting metrics and thresholds actually takes place – particularly if a metric or threshold is likely to place an entity or group in a higher risk category.

Finally, risk-informed regimes are intended to reduce burden for strong performers and to increase it when performance is lagging (according to a range of different responses). But this may implicate significantly *more* regulatory activity and responsibilities for regulators and their non-governmental partners, particularly in the early years of transition to the new system. These challenges do not negate the benefits—but policymakers should approach risk-informed regimes fully aware of the potential investments that are certainly implicated and the downsides that may be centrally relevant to any such endeavor.

²⁶ This discussion was informed significantly by several scholarly sources, particularly Coburn and Weddle, *supra* note 1; Baldwin and Black, *supra* note 15; Financial Services Commission of Ontario, *supra* note 24; as well as the various U.S. and international models discussed in Section III *infra*.

Risk-Informed Decision Making in American Higher Education

Incorporating risk into decision making is not a foreign concept to American higher education. Indeed, many colleges and universities already embed risk assessments into strategic planning efforts and employ a chief risk officer. Many even develop their own impact versus probability charts similar to the graphic on page 10 to determine which risks to accept, monitor, or mitigate and control. And, as a response to institutions' tendency to focus on risk only in the negative, the University Risk Management and Insurance Association (URMIA) was founded by various U.S. institutions to promote a more positive view of risk management in universities.

Moreover, accrediting agencies—key actors within the federal regime who address issues of institutional and provide quality—have begun to incorporate risk into their accreditation decision making process. For example, the Western Association of Schools and Colleges Senior College & University Commission (WASC Senior) has developed considerable variability in its responses to findings of accreditation reports similar to the “red-yellow-green” responses described earlier in this paper. Depending on the level of strength (and level of risk, determined holistically), WASC Senior varies the term of years before the next required accreditation review cycle from seven to ten years. For institutions demonstrating a need for close monitoring, WASC Senior has tiers of follow-on requirements (e.g., progress reports, special visits, and notices of concern).

These developments in the higher education community illustrate the appeal of incorporating risk into the regulation of higher education. The concept is already familiar to the regulated community of institutions and has been a useful tool for these complex organizations to bring greater prioritization and focus to their work. It comes as little surprise, then, that the concept has been endorsed in current postsecondary legislative proposals. One draft HEA reauthorization bill calls for ED to conduct “risk-based reviews” for at least two percent of IHEs for program reviews (and names several conditions for prioritization of reviews). And draft bill to reauthorize the COMPETES Act includes a provision that requires the study of risk-based regulatory procedures for determining requirements for evaluation requirements for federal research awards.

III. HOW RISK-INFORMED AND RISK-BASED REGULATORY APPROACHES HAVE BEEN PURSUED AND APPLIED IN OTHER SETTINGS

Before launching into recommendations for new risk-informed regimes in the regulation of higher education, a careful examination of more mature risk-informed systems is called for. At a basic level, these illustrations bring this paper's general discussion of the functions and design elements to life. And understanding these systems, both in design and execution, can significantly enhance perspectives regarding the prospective improvement of our higher education system—may help inform the identification of viable areas of higher education regulation that are strong candidates for adoption of new risk-informed systems. This section explores existing risk-informed and risk-based systems in multiple sectors in the U.S. as well as risk-informed systems being developed in postsecondary regulatory systems in Australia and the United Kingdom.

A. Illustrations from Other Sectors

Risk-informed and risk-based systems have their origins in the latter decades of the 20th century, when industrialized nations became more interested in deregulation initiatives and a shift toward the private sector-style management methods including the use of cost-benefit analyses. The Nuclear Regulatory Commission provided early leadership in the field of American regulation, while the Basel Accords on requirements for capital systems

led the way internationally through a voluntary series of agreements. Today, risk-informed approaches have been established or are emerging in a variety of sectors, including the regulation of scientific laboratories and health information technology firms.

Risk-informed regulation has been used in some form by the Nuclear Regulatory Commission (NRC) since the late 1970s.²⁷ Its status as an early adopter and decades of experience with these systems make the NRC an appropriate starting point. Indeed, the NRC conducted a rigorous review of regulatory approaches before adopting its risk-informed system, which has served as guidance for this paper and for many others on risk-informed regimes.²⁸ The NRC's risk policy mandates that the risk of cancer fatalities of people living near a nuclear power plant cannot exceed 0.1 percent of the sum of cancer fatality risks from all other sources, and licenses will only be given to power plants who meet the requirements in the policy for an acceptable level of safety to the public.²⁹ The Commission complements these requirements with regulations based on probabilistic risk assessment (PRA) to assess the likelihood and consequences of severe reactor accidents.

The Federal Reserve Board oversees a risk-informed capital system that weighs the risks inherent in the different types of loans offered by a bank and determines how much capital a bank needs to possess in order to be protected upon default. This system is part of a voluntary, global effort that started in the 1970s in response to the increasing internationalization of economies and capital flow—and the large foreign currency losses many banks were experiencing when the system allowed a bank to have three times the exposure in foreign markets than its available capital.³⁰ Foundations were laid during a 1975 meeting of the G-10 countries, followed by successive Basel Capital Accords among many countries.³¹ “Basel III” is currently being implemented, which includes significant changes to respond to banking strategies that led to the global financial crisis.³² Notably, the same problem that led to Basel I—too much exposure and not enough capital—was a significant reason for the financial crisis in 2007–09.³³ This history demonstrates the importance of remaining grounded in the original purpose of the system, but revising standards and metrics to meet new challenges.

The success of the Basel Accords has led to risk-based capital rules being expanded to financial institutions in the U.S. other than banks. The National Association of Insurance Commissioners, a standard-setting and regulatory support system created by the insurance regulators from each state, also employs a risk-based capital system based on the Basel Accords to ensure that insurance companies have adequate levels of capital.³⁴ And other countries have expanded Basel principles even further, with some converting all financial regulation to a risk-based system.

Since 1976, the Food and Drug Administration (FDA) has used a risk-based approach to classify medical devices, using the degree of control necessary to assure the safety and effectiveness of the devices as a risk barometer.³⁵ The

²⁷ Coburn and Weddle, *supra* note 1.

²⁸ William D. Travers, Risk-Informed and Performance-Based Regulation (March 1, 1999), <http://www.nrc.gov/reading-rm/doc-collections/commission/srm/1998/1998-144srm.pdf>.

²⁹ U.S. Nuclear Reg. Comm'n, Fact Sheet on Nuclear Reactor Risk (June 30, 2014), <http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/reactor-risk.html>.

³⁰ Bank for Int'l Settlements, History of the Basel Committee, <http://www.bis.org/bcbs/history.htm> (updated Oct. 28, 2014).

³¹ *Id.*; Capital Standards for Banks: The Evolving Basel Accord, Fed. Reserve Bulletin 395 (Sept. 2003).

³² Basel Comm. on Banking Supervision, Basel III: A global regulatory framework for more resilient banks and banking systems 2 (rev. June 2011), www.bis.org/publ/bcbs189.pdf.

³³ *Id.*

³⁴ Nat'l Ass'n of Insurance Comm'rs, Risk Based Capital General Overview 1 (2009) http://www.naic.org/documents/committees_e_capad_RBCoverview.pdf.

³⁵ The statutorily created device classes are: (1) Class I devices are generally low risk and are mostly exempt from premarket review and are subject—unless exempt—to the requirements for reporting of adverse events, manufacturing and design controls, registration and listing, and other “general” controls. Surgical apparel and surgeon's gloves are examples of Class I devices. (2) Class II devices implicate

FDA has created a comprehensive listing of about 1,700 types of medical devices, each of which has been assigned one of three risk categories. The success of this approach led Congress to instruct the FDA, in consultation with other relevant federal agencies, to propose a strategy and recommendations on “an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication for a health information technology (health IT) framework.”³⁶ The resulting report proposes to clarify oversight of health IT products based on a product’s function and the potential risk to patients who use it.³⁷ The report makes an instructive observation for many sectors in its discussion, “Ultimately, the Agencies recognize that any categorization scheme will be imperfect and may need to adapt over time. Nevertheless, we believe that this proposed functional categorization can both assist the Agencies in avoiding regulatory duplication and prompt meaningful policy discussions with stakeholders to identify and clarify unresolved areas of ambiguity.”³⁸

B. International Examples in Postsecondary Education

Even though important contextual differences exist, experiences in other countries can be useful illustrations of how the design and implementation of risk-informed regimes has worked in practice. This section explores systems in Australia and the United Kingdom.

1. Australia

In Australia, the Tertiary Education Quality Standards Agency (TEQSA) began operating in 2012 as the national quality standards agency for the 37 public institutions, four private institutions, and 131 other providers that make up the Australian system of higher education.³⁹ TEQSA’s establishment followed on the opening of Australia’s public institutions in 2009 to a “demand-driven” system as caps on bachelors-degree enrollment were removed and institutions were allowed to increase enrollment based on student demand.⁴⁰

Under TEQSA, Australian degree-granting institutions have the authority to self-accredit their courses through academic boards or similar internal bodies. But they must do so under the Higher Education Standards Frame-

generally moderate or well-understood risks, are subject to general controls, are usually subject to premarket review, and subject to enumerated “special controls” that are closely tailored to the specific risks presented by that particular device type. Ear, nose, and chin prostheses are examples of Class II devices. (3) Class III: Devices that generally present high or poorly understood risks. In addition to general controls, Class III devices are subject to premarket approval and certain other regulatory controls. A special injectable paste designed to augment or reconstruct a vocal cord is an example of a Class III device. Food and Drug Admin. (FDA), Overview of Device Regulation, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm> (last updated June 26, 2014); FDA, Device Classification Panels, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm> (last updated June 26, 2014); FDA, FCC, ONC, FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework 29, n.76 (April 2014), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf>.

³⁶ FDASIA Health IT Report, *supra* note 42, at 3.

³⁷ The three risk categories within the proposed system are: (1) Products with administrative health IT functions that pose little or no risk to patient safety and thus require little to no additional oversight or attention (e.g., software for billing, claims processing, and scheduling). (2) Products with health management health IT functions that pose sufficiently low risk so they do not require significant oversight (e.g., software for health information and data management, electronic access to clinical results, and clinical decision support software). For this category, the FDA proposes relying primarily on coordinated regulatory activities among different agencies, supported by private sector capabilities, and tools for testing, certification, and accreditation. (3) A final group of products with medical device health IT functions that pose greater risks to patients if they do not perform as intended (e.g., computer-aided detection software, software for bedside monitor alarms, and radiation treatment software). The FDA proposes to continue regulating these products as it currently regulates all health IT functions. *Id.* at 11-13.

³⁸ *Id.* at 11.

³⁹ Hon. Dr. David Kemp and Andrew Norton, Review of the Demand Driven Funding System—Final Report 77 (2014), http://docs.education.gov.au/system/files/doc/other/review_of_the_demand_driven_funding_system_report_for_the_website.pdf.

⁴⁰ Discussion of the Australian system was informed by an interview with Andrew Norton, co-author of the report cited in note 34, and several representatives of Australian institutions, which took place on October 22, 2014. Notes from the interview on file with the authors.

work and they must be registered annually with TEQSA. (TEQSA also approves each course at most non-institution providers through a separate process.)

TEQSA's actions represented a significant change for Australian institutions because, prior to 2012, most regulation was conducted through state governments. Though states took different regulatory approaches (some were more expansive than others), they generally adopted a very light touch regulatory approach. But in the first decade of the 21st century, Australia—like the U.S.—saw a large expansion in the higher education and vocational training sectors driven by growing student populations (particularly international students) and demand for financial aid. The failure of some new institutions and some questionable student recruitment practices led to increased scrutiny of oversight regimes for institutions. A review in 2008 of Australia's postsecondary funding system triggered a broader legislative effort to create a more rigorous national system of regulation by enhancing requirements that public institutions participate in a national quality agency's review process as a condition for qualifying for student aid from the national government. Policymakers also saw a more rigorous quality control system as a precondition for expanding aid programs to students at private institutions.

Notably, risk assessment was embedded in the TEQSA bill by the Australian Parliament on the recommendation of the higher education community.⁴¹ An early bill would have created a much more prescriptive agency to mirror Australian agencies in other sectors. The Australian higher education sector responded by proposing that regulation be determined in proportion to risk. The final law was initially seen as a victory by Australian institutions.

Under that law, TEQSA's review process for degree-granting institutions includes an initial review using three guiding principles: risk assessment, proportionality, and intervention only when necessary. Through its risk assessment framework and the use of risk assessments, TEQSA aims to:

- Reduce regulatory burden by using risk assessments to inform a differentiated approach to evidence and reporting requirements;
- Strengthen the protection of students' interests and the sector's reputation by monitoring key aspects of providers' operations during review periods;
- Encourage TEQSA case managers and providers to engage early with providers about emergent issues; and
- Support quality improvement by sharing information with providers about potential risks and good practices in the sector.⁴²

Importantly, TEQSA uses risk assessments to identify potential risks of non-compliance (or "leads" that warrant additional consideration by TEQSA case manager)—*not* to draw conclusions about compliance with regulatory or other legal standards.⁴³ Instead, TEQSA uses the risk assessment as a basis for determining how to respond to providers based on the issues identified in the risk assessment.

TEQSA defines risk in four key areas: (1) regulatory history and standing; (2) student profiles and outcomes (measured by student load, student attrition rate, progress rate, completions, student satisfaction, and graduate

⁴¹ Incorporation of risk in TEQSA's process was partially due to the fact that, during the global financial crisis, Australia's banking system survived mostly intact – which much of the Australia public attributed to Australia's risk-based financial regulatory system. This public sentiment influenced the Australian government's reauthorization of higher education-related legislation in 2011. TEQSA, A Snapshot of TEQSA (2013); Self-Accrediting Authority, TEQSA (2012), <http://www.teqsa.gov.au/for-providers/self-accrediting-authority>.

⁴² Australian Government Tertiary Education Quality and Standards Agency, TEQSA's Risk Assessment Framework Version 2.0 2 (March 2014), http://www.teqsa.gov.au/sites/default/files/publication-documents/TEQSARiskAssessFramework2014_0.pdf.

⁴³ Id.

destination); (3) academic staff profile (measured by qualifications of senior academic leaders, student to staff ratio, and academic staff on casual work contracts); and (4) current and historical financial viability. TEQSA has developed a list of specific risk indicators for each area⁴⁴ and TEQSA's evaluation uses a simple rating system of high, moderate, or low risk (represented by traffic colors) for each.

Risk thresholds are considered in the context of other information and are not the sole determinants of risk. For annual risk assessments of institutions, TEQSA considers past and present documentation and reference material, statistical analysis of the sector, experience from previous risk cycles, and any special considerations related to the nature of the indicators.⁴⁵ TEQSA keeps the actual numeric thresholds confidential, but does publish its standard thresholds.⁴⁶ Providers are thus aware of general expectations and what data and information will be assessed, but are unaware of the precise point at which their risk drops below a risk threshold.

TEQSA combines the information from these sources and makes a judgment about the risks of the provider against the identified threshold. Importantly, TEQSA's overall evaluation examines both risk to an institution's *students* and risk to its *financial position*.⁴⁷ TEQSA calculates risk holistically, meaning even when a higher education provider falls below a threshold, success in other priority areas may balance the provider's overall quality, eliciting less or no regulatory response from TEQSA.⁴⁸ From this rating, TEQSA takes one of the following five steps:

1. Formal regulatory action outside the scheduled review process, e.g., undertaking a compliance assessment or imposing formal conditions on registration for institutions
2. Consideration of issue during scheduled regulatory review
3. Formal request for information
4. Recommendation that the institution carefully monitor and/or put into place appropriate controls or improvement strategies
5. No action⁴⁹

TEQSA keeps its risk assessments confidential, and only shares them with providers if the institution receives an overall moderate or high risk rating, has significant gaps in data (or otherwise causes TEQSA to have no confidence in the data), requests a copy, or faces registration renewal.⁵⁰ Because of this—and the fact that TEQSA relies on existing information in its systems (e.g., providers' annual reporting requirements)—burdens on providers are limited. In many cases, providers do not have any responsibilities to interact with unless there is an identified issue. In other words, low-risk providers have very low burdens related to TEQSA's risk assessment.

TEQSA's early years have not been without controversy. Australian institutions broadly endorsed these design elements (including the incorporation of risk-informed regimes), but believed that TEQSA pushed an overly prescriptive interpretation of statutory requirements, mandating significant new reporting requirements and pouring significant staff time into institutional reviews that went beyond the intentions of the Parliament.⁵¹

⁴⁴ Id. at Appendix 1.

⁴⁵ Id. at 6.

⁴⁶ Id.

⁴⁷ Id. at 5.

⁴⁸ Id.

⁴⁹ Id. at 8.

⁵⁰ Id. at 4.

⁵¹ Part of the challenge for the longstanding public institutions is that they had long enjoyed very light regulation and a reputation for quality. But, when TEQSA was established, institutions suddenly had to provide data and information to support their claims of quality.

Another challenge was that TEQSA had been established before Australia's national standards for postsecondary quality were revised (a process that has now been initiated), meaning that TEQSA lacked important foundations to justify its more outcomes-oriented approach. As a result, the Australian Parliament commissioned a study of TEQSA's performance, which concluded, "TEQSA, while subject to criticism for bureaucratic over-reach, is now effectively preventing sub-standard higher education courses in both public and private institutions. The existence of a system of standard setting, with appropriate monitoring and enforcement, has a significant bearing on any decision to expand the scope of the demand driven system."⁵²

As a result of the report and mounting political pressure, several actions were taken to reduce burdens on institutions and to streamline TEQSA processes. TEQSA deemed 2013–14 the "year of reform" and reduced evidence requirements by tailoring assessment processes for low risk providers; reduced timelines for completing course accreditation and re-accreditation assessments; and reduced annual risk assessment requests for information by drawing on existing data.⁵³ TEQSA has also increased its efforts to engage with the higher education sector. Finally, significant personnel changes have taken place in 2014, with the founding chief commissioner of TEQSA placed on leave in June 2014 and the agency staff significantly downsized—deliberate decisions to force TEQSA to focus its review process on the most essential elements.

Notably, the concept of risk within the TEQSA system has not been the target of critics and remains a regulatory concept that both the government and institutions support.⁵⁴ The challenge for TEQSA now will be to develop proportional procedures that reduce burdens on low risk providers and focus agency resources on high risk providers.

2. *United Kingdom (U.K.)*

The British context mirrors that in Australia in two key ways. First, the U.K. is currently moving toward a more "market-based" system of higher education that allows for enrollment in institutions to be based not on pre-allocated quotas but on student demand. Second, Higher Education Funding Council for England (HEFCE)—a public body not situated in any government department or agency—is moving toward a risk-informed system in which regulators will conduct fewer and less frequent reviews on institutions that have long records of quality in higher education and more thorough and frequent review of institutions with short records or records lacking quality.⁵⁵

HEFCE acts as a broker between institutions and the U.K. government with authority to determine the conditions for government funding for institutions and to distribute those funds.⁵⁶ Under a new framework released in

⁵² Kemp and Norton, *supra* note 46, at 3. Other specific findings from the report included:

- All existing institutions "aware that their actions and performance, including any rapid expansion under the demand driven system, are potentially subject to scrutiny from TEQSA."
- Though not a formal complaint resolution agency, TEQSA keeps records of complaints and, when "multiple credible complaints suggest there may be a significant problem, TEQSA is able to investigate further."
- New institutions and providers face "a very significant barrier to entering the higher education system" by virtue of TEQSA's registration process.
- TEQSA's standards are rigorous, and the body "has rejected provider registration and course approval requests that do not meet the standards and has applied conditions to other approvals to ensure that the standards are met." The report concludes, "This third-party scrutiny contributes to our confidence that Australia's higher education system can accommodate increasing numbers of students and higher education providers without compromising quality."

⁵³ Australian Government Tertiary Education Quality and Standards Agency, TEQSA Annual Report 2013-14 2 (tabled in Parliament Oct. 24, 2014), http://www.teqsa.gov.au/sites/default/files/publication-documents/TEQSA2014AnnualReport_FullReportWeb.pdf.

⁵⁴ Norton et al. interview, *supra* note 47.

⁵⁵ UK Dept of Bus., Innovation and Skills, Higher Education: Students at the Heart of the System 10 (2011).

⁵⁶ HEFCE, Memorandum of assurance and accountability between HEFCE and institutions: Terms and conditions for payment of

the summer of 2014, HEFCE includes confidential risk assessments as conditions of funding. These assessments use institutions' annual accountability reports (a requirement for funding eligibility), outputs of the institution's internal and external auditors, information from other public bodies, and HEFCE's own audit and assurance work.⁵⁷ Results are provided to the applicable institutional leaders.⁵⁸ These risk assessments will normally remain confidential for three years, and then be released to the public. HEFCE considers this three-year period to be an appropriate period of time to allow institutions found to be high risk to address issues and reduce its classification.⁵⁹

HEFCE judges an institution to be "at higher risk" when, on the basis of all available evidence, it:

- Faces threats to the sustainability of its operations, either immediately or in the medium term,
- Has serious problems relating to value for money, propriety or regularity (that is, whether funds are used for the purpose intended), or
- Has materially ineffective risk management, control, or corporate governance.

When it judges that an institution "does not meet" or "requires improvement to meet" its standards then fails to make the necessary improvements through a relatively low-burden follow-up process, HEFCE will step in and require regular meetings. HEFCE has explained that its greater involvement in such cases is justified "because it has a clear regulatory interest to ensure that [institutions] in receipt of public funds provide value for money and are responsible in their use of these funds."⁶⁰ HEFCE expects institutions in this process to improve. If improvements do not occur, however, HEFCE may apply sanctions in "exceptional" cases, including the withdrawal of some or all HEFCE funding.

Implementation has gone more slowly than initially proposed due to the concern from the field that the categorization and ranking of higher education institutions could pose political challenges, could create a large burden from initial investment as regulated groups compile the necessary data, and could place more regulatory burdens on new institutions than under the old regulatory scheme.⁶¹ Though HEFCE has implemented the new risk assessments, it is still working with stakeholders to determine appropriate risk thresholds.⁶²

IV. PRINCIPLES TO GUIDE ACTION AND PROSPECTIVE RISK-INFORMED REGIMES TO CONSIDER

Developing effective risk-informed regimes that are a net benefit to regulators, their non-governmental partners, and the regulated community requires a significant investment of time and resources from many different stakeholders. Any new regimes will likely take many months to be designed and many years to mature. Moreover, new or enhanced risk-informed regimes are likely to require traditional regulatory structures to give way to new requirements and processes. And they will need to be coherently integrated into a larger regulatory regime that

HEFCE grants to higher education institutions 1 (June 2014), http://www.hefce.ac.uk/media/hefce/content/pubs/2014/201412/HEFCE2014_12.pdf.

⁵⁷ Id. at 20-21.

⁵⁸ Id.

⁵⁹ HEFCE does allow for limited release of risk assessment results before the three years have elapsed in two exceptional cases: (1) if other public funders and other regulators to need the results to make their own assessments of risk, or (2) if the National Audit Office needs to discuss the results at the Public Accounts Committee or disclose them in a published report. Additionally, HEFCE will make results public (after notifying institutions) at any stage if it has "strong grounds for believing that it is in the collective student or the public interest to do so." Id. at 4-5.

⁶⁰ Id.

⁶¹ Roger King, *The Risks of Risk-Based Regulation: The Regulatory Challenges of the Higher Education White Paper for England* 3-7 (2011).

⁶² See HEFCE, *supra* note 63.

will likely include other non-risk-informed provisions. In addition, regulators and the regulated community must have confidence in each other that the new regime will be designed and implemented—and responded to by institutions—in good faith. Otherwise, prospects for success are likely slim. Policymakers should initiate this process, therefore, with clear eyes about what new legislation or regulation will precipitate and what investments and commitments from various stakeholders will be required.

This section provides guiding principles for developing risk-informed systems, starting with the conditions that must be in place before starting the process and then exploring key factors for system design, implementation, and evaluation and improvement.⁶³ With these principles in place, the second half of this section identifies prospective opportunities for risk-informed regimes within the current federal postsecondary regulatory system.

A. Guiding Principles

Based on the theory associated with risk-informed regulation and lessons that have emerged during the implementation of other regimes, we have identified the following principles to inform the assessment of necessary prerequisite conditions and to guide action for the development, implementation, and continuous improvement of specific risk-informed regimes. These principles are intended to be applied in specific, discrete regulatory contexts—not to guide the complete overhaul of the federal regulatory system for institutions of higher education.

And it is important to understand the difference between the fundamental risk in the federal regulation of higher education and the specific risks that provide the foundation for risk-informed regimes. The fundamental risk entailed in the federal regulation of higher education is tied to the federal investment in financial aid and the desire to protect students and to be a good financial steward for the taxpayers' dollars. In other words, the overall risk in the system is that students use federal financial aid (and, therefore, taxpayer dollars) to pay for low quality postsecondary programs that do not enhance their professional prospects. This broad risk should motivate all of federal regulation of institutions. But it is essential to distinguish this broad risk from the specific risks that must be identified for risk-informed regulatory regimes. In those cases, the risk must be related to a more specific problem that is directly tied to a particular area of regulation, e.g., the risk of mismanaging federal financial aid dollars through problematic disbursement or refund processes.

Necessary prerequisite conditions (i.e., conditions that must be in place before any risk-informed regime is even considered)

- A risk-informed regulatory regime should only involve areas where regulators have clear authority to develop a risk-informed regime or significant discretion in determining regulatory response. Granting accrediting agencies flexibility to establish risk-informed review procedures (as explored in more detail later in the paper) is likely to be an appropriate area, while using a risk-informed system to enforce federal civil rights laws is not, given the legally mandated statutory and constitutional rights and protections associated with individual student rights that dictate permissible regulatory parameters.
- Risk should be defined very precisely and concretely. The examples of successful risk-based and risk-informed systems described above started first with the question of the risk or danger to be avoided (e.g., cancer rates for nuclear power plants), and built the system from there.

⁶³ These principles were distilled from a range of scholarly sources, interviews with practitioners, and policy best practices, particularly Coburn and Weddle, *supra* note 1; Baldwin and Black, *supra* note 15; Financial Services Commission of Ontario, *supra* note 24; as well as the various domestic and international models discussed in Section III *supra*.

- The regulatory area should have some type of *prospective* risk involved.⁶⁴
- The regulatory area should implicate a risk that is measurable through existing data sources.⁶⁵
- There should be some evidence that regulated entities are likely to fall under each level of risk defined. In other words, the risk thresholds should relate to known variances in performance related to the risk in question, even though the precise lines between thresholds should not be drawn at the outset.
- Regulators should be able to develop a range of potential regulatory responses that are specifically tailored to the different levels of identified risk. This process likely provides an opportunity for regulators and their non-governmental partners to be more systematic and strategic in how they allot technical assistance, make requests for additional information, and impose more severe consequences.

Potential key questions to assess necessary prerequisite conditions:

- Is the risk in question real and easily understood? Does it implicate a specific area of regulation?
- Do the likely benefits of the prospective risk-informed regime outweigh the likely challenges (both in the short and long term)?
- Does stakeholder support exist for the concept of shifting to a risk-informed regime *and* are stakeholders committed to the hard work of turning the concept into an actual regulatory regime?

System design

- The system should incorporate the five key functions present in mature regimes (from pages 8-9):
 1. Defining the purpose and goals of the system in terms of specific risks
 2. Determining the responsible agency or organization's own risk appetite
 3. Assessing the risk and its likelihood of occurrence
 4. Assigning scores or ratings to regulated entities on the basis of risk assessments
 5. Linking regulatory responses and resources to scores or ratings categories (for individual regulated entities and/or for system-wide issues)
- The type of risk in question and the different thresholds for performance should be clearly defined by regulators (and, in some cases, enforcement partners such as accrediting agencies), with the input of the full range of stakeholders.
- Data and information sources to determine and monitor risk should be clearly defined before any assessment of risk takes place.
- Thresholds should be based on accessible and reliable data and information sources—and collection should be based on existing sources and through existing collection methods wherever possible to avoid duplication of existing reporting requirements.

⁶⁴ A risk-informed system would be inappropriate for retroactively adjusting the regulatory response for violations that have already occurred. In the higher education context, a risk-informed system would be inappropriate for re-designing USED's procedures for assessing fines for past violations by institutions of federal rules. The fact that USED's fine assessment procedures might benefit from greater flexibility—an objective shared by risk-informed regimes—does not mean that the entire regulatory action can be designed according to the principles in this paper because the two regulatory functions are fundamentally different (creating conditions for monitoring, as opposed to imposing consequences when violations are made).

⁶⁵ This is not to say that new data sources should not be developed to build a smarter, more effective regulatory system. Indeed, new prospects for risk-informed regimes may emerge in time. But this paper focuses squarely on the prospect of developing viable risk-informed systems today (and not on how to develop new data sets), meaning that existing data sources are an appropriate necessary condition.

- Regulatory responses should be tiered and should be defined in direct relation to the types of risk that they are intended to address.
- If systems are defined as “opt in” by institutions, every effort should be made to avoid the creation of multiple regulatory regimes that may conflict or overlap with one another.
- Regulated entities and other stakeholders should be given multiple opportunities to contribute to and comment on the proposed system design elements.

Potential key questions to assess system design:

- What body is the most efficient and effective entity to maintain oversight or control over the contemplated risk informed regime?
- What are the risk variables at the top of the hierarchy? Are the metrics that are incorporated into the risk determination primarily outcome measures that related directly to the defined risk areas for the regime?
- Do proposed metrics and thresholds appropriately allow for differences in institutional mission and students served? Are all institutions implicated by the regime responsible under similar performance standards that may nevertheless be applied by regulators in a way that appropriately accounts for different contexts?
- Who should be responsible for defining the risk and identifying appropriate metrics and thresholds? And based on what process?

System implementation

- The primary oversight body and enforcer of the new risk-informed regime should be prepared for an initial investment of time and resources to set up the regime, to provide information and technical assistance, and to conduct a baseline assessment for regulated institutions. Regulated institutions will also need to invest resources into understanding and complying with the new requirements.
- Piloting of the system for a small number of regulated entities may be an important foundation for informing how risk is defined and assessed over time. No binding regulatory response should take place for at least the early phase of the pilot.
- Regulated entities and other stakeholders should be given multiple opportunities to comment on the implementation process to inform final processes and system elements.

Potential key questions to assess system implementation:

- Are all system participants prepared for the initial investment of time, effort, and resources—and clear about the longer-term payoff for this investment?
- Are regulators prepared and empowered to make mid-course corrections when problems arise?

System evaluation and improvement

- Regulators should regularly review overall system performance, with special attention to tracking how institutions are categorized on the basis of risk and what types of regulatory responses are most common. Adjustments should be made as appropriate.
- Regulatory burden should also be regularly assessed, both for regulated institutions and for regulators. Adjustments should be made as appropriate.

- The definition of risk, how it is assessed, and how regulators respond should be regularly revisited and revised.

Potential key questions for system evaluation and improvement:

- How can the regime mitigate unanticipated, unforeseen, or misunderstood elements of the definition of risk, the identified thresholds and metrics, and the appropriate regulatory responses? Can these be mitigated?
- Does the regime tend to affect certain types of institutions in unique ways? Are any institutions experiencing negative consequences due to student demographics and other factors outside the institutions' control?

ED's Financial Responsibility Standards

ED has a risk-informed system for assessing private nonprofit and for-profit institutions' financial viability for purposes of Title IV funding eligibility. In the late 1990s—based on a congressional mandate in the 1992 amendments to the HEA—ED worked with a variety of stakeholders and commissioned a task force and expert report to inform methods of calculating financial ratios to identify financially troubled institutions. The process of calculating these ratios was intended to provide an “initial screening” through which ED could “appropriately allocate its limited resources to more financially at risk institutions.” This initial design and implementation process was largely considered a success by the higher education community.

The current system is largely unchanged from what was established in the late 1990s. One key measure is the “financial ratios test,” which draws on institutions' annual financial statements to create a ratio for each institution on a scale of -1.0 to 3.0. Those institutions with a score of 1.5 or above are considered financially responsible, and no other requirements apply. Institutions with scores between 1.0 and 1.4 may continue to receive federal funding, but are required to submit to additional monitoring and oversight requirements. Institutions with scores below 1.0 only remain eligible for Title IV funding if they provide additional surety, such as a letter of credit equal to a minimum of 10 percent of the Title IV aid received in the institution's most recent fiscal year.

After the financial downturn of 2008–09, more than 100 non-profit colleges unexpectedly “failed” the financial ratios test by receiving scores under 1.5, due in large part to decreases in endowment funds. Many of these colleges were forced to obtain letters of credit to maintain their Title IV eligibility, which can be an expensive, time-consuming endeavor. As a result, the National Association of Independent Colleges and Universities (NAICU) established its Financial Responsibility Task Force to review the ED's process for determining institutions' fiscal viability. In November 2012, the Task Force released its final report, which called into question ED's financial review procedures. The report made several recommendations, including that ED's financial responsibility system be revised to reflect generally accepted accounting principles that have been revised since the 1990s, particularly with regard to the assessment of changes in endowment funds, and that ED should convene a new panel of accounting experts to provide technical guidance in that effort.

Though these issues have yet to be fully resolved, this experience illustrates the importance of regularly engaging with stakeholders and technical experts to ensure that risk-informed systems remain current and relevant over time. It also shows the difference between the viability of a risk-informed regulatory approach from challenges or problems that may be part of the implementation and continuous improvement of such an approach.

B. Prospective Risk-Informed Regimes

Building on the principles explored in the preceding section, the following discussion provides a beginning list of sample policy areas where risk-informed reform might be undertaken in higher education. Each of these areas meets the “necessary prerequisite conditions” identified—though, in some cases, changes in regulations or statute may be necessary. These prospective regimes also represent opportunities to reduce compliance burdens significantly and to direct ED’s enforcement efforts more meaningfully. Significant stakeholder engagement will be necessary for the successful design and implementation of any of these regimes, and this list is intended only to provide concrete examples of potentially ripe areas for risk-informed regulation in the existing federal regulatory system for colleges and universities.

Requirements for financial aid reporting could be restructured around a risk-informed regime. The bulk of the reporting burden for institutions in reporting student financial aid information is not necessarily the annual reporting that takes place through IPEDS for accountability, completion, and other purposes. Instead, the bulk of the burden comes through the bimonthly updates that financial aid offices are required to submit through the NSLDS system for Direct Loan compliance and with the Department of Defense for financial aid programs for veterans. These updates are intended to track the changes in enrollment that may cause students to fall out of eligibility for federal financial aid programs (and, therefore, the institution is in improper receipt of federal funds after the funds have been disbursed to students). For institutions that have stable student populations and/or a history of sound financial accounting practices and appropriate return of federal funds (among other indicators), a risk-informed system could reduce the frequency of reporting requirements. For example, institutions deemed low risk might be subjected to only the annual accounting process, those deemed medium risk could have quarterly reports due, and those deemed high risk could continue to be subjected to the bimonthly updated reports.

- *The risk.* The risk is that institutions are promoting fraud in the use of federal funds in cases where students fall out of eligibility for some or all of their federal financial aid during the semester or school year.
- *Benefits.* This system could significantly reduce compliance burdens for both low risk institutions and for ED.
- *Challenges.* The system would mean that at least some institutions would be providing much less frequent reports to ED, which may prompt regulatory oversight concerns.

Accrediting agencies could have clear authority to develop risk-informed approaches to reviewing and taking action regarding institutions.⁶⁶ Approaches could encompass new policies for both strong performers (e.g., expedited review) and low performers (e.g., consequences other than removal of accreditation status)—guided by a system for differentiating between levels of institutional performance. It should be noted that accrediting agencies have already explored and implemented some risk-informed concepts, including tiered consequences based on review findings. The prospective regime contemplated here, however, would allow accreditors to develop more robust systems that could tie to new, more nuanced requirements in the HEA. In other words, rather than a determination of “accredited or not” for Title IV purposes—leaving aside the more nuanced judgments accrediting agencies make within their peer review processes described above—systems could potentially allow for strong performing, low-risk institutions to receive an expedited review and/or for low-performing, high-risk institutions to be targeted and supported more effectively through the accreditation process.

⁶⁶ The application of this prospective regime (at least for expedited review for strong performers) has been endorsed by ACE, AAU, and APLU, among others, in recent comments submitted to the Senate HELP Committee on Senator Harkin’s discussion draft bill. See note 2, *supra*.

- *The risk.* The central risk implicated is that of the accreditation process failing to identify weak institutional performance and take action before students are unduly harmed.
- *Potential benefits.* Accrediting agencies already make very context-specific assessments of institutional performance as part of the accreditation process; developing more systematic risk-informed systems may reduce burdens for institutions with a history of strong performance, allow accreditors to be more systematic in targeting resources, and provide additional transparency in the accreditation process. And because they work with groups of relatively similar institutions (either in terms of region/geography or institutional sector) accrediting agencies can work more quickly and more closely with their institutions on new approaches than if ED attempted to design and implement a risk-informed system for all of higher education. These approaches also promise to reduce burden on institutions that present low risk, thereby freeing more of their resources to go toward students.
- *Potential challenges.* Most importantly, developing new risk-informed systems within accrediting agencies may be a significant new burden for ED, for accrediting agencies, and for institutions, at least in the design and early implementation process. Also, the approaches developed by different accrediting agencies may differ in key areas. For example, accrediting agencies (particularly the regional accrediting agencies), accredit a wide variety of institutions, which may make it challenging to develop metrics and thresholds that can apply in a variety of institutional contexts.

ED could establish a risk-informed regime for the program reviews conducted by the Federal Student Aid (FSA) office. Approximately 300 reviews are undertaken each year, and encompass assessments of whether the institution under review meets requirements for institutional eligibility, financial responsibility, and administrative capability for purposes of Title IV compliance.⁶⁷ The HEA identifies a few prospective triggers for a program review, but leaves significant discretion to ED.⁶⁸ ED currently does not publish how it selects the institutions to undergo program reviews. Policymakers have already identified this area of ED’s authority as ripe for potential risk-informed systems, as demonstrated, for example, in Senator Harkin’s draft HEA reauthorization bill that would direct ED to build in “risk-based” program reviews annually for two percent of institutions participating in Title IV.⁶⁹

- *The risk.* The risk is that institutions are inappropriately using federal financial aid funding, to be primarily measured by student outcomes. Some metrics may include those already embedded in the HEA: a cohort default rate over 25 percent; a cohort default rate in the top 25 percent of all institutions; significant fluctuation in Stafford Loan, Direct Loan, or Pell Grant volume; identified deficiencies or financial aid programs identified by the relevant state or accrediting agency; and high annual dropout rates.⁷⁰

⁶⁷ During a program review, reviewers evaluate the school’s compliance with requirements, assess liabilities for errors in performance, and identify actions the school must take to improve its future administrative capabilities. Federal Student Aid, Program Reviews, <https://studentaid.ed.gov/about/data-center/school/program-reviews> (last accessed Oct. 26, 2014).

⁶⁸ HEA § 498A, 20 U.S.C. § 1099c; see also Federal Student Aid, Program Review Guide for Institutions (2009), <http://www.ifap.ed.gov/programrevguide/attachments/2009ProgramReviewGuide.pdf>.

⁶⁹ Specific considerations may include large increases in funding over a five-year period, a large proportion of overall federal funding, significant fluctuation in federal funding, sharp increases in enrollment, high default rates, high student default risk, high proportion or rate of complaints, low graduation rates, poor financial health, large proportion of funding toward recruiting and marketing, large profit margins [for proprietary institutions], negative action by an accrediting agency, prior compliance problems, large amounts of federal funds returned, and change in ownership [for proprietary institutions]). The bill allows USED to determine the final specific criteria as well as the processes for conducting for such reviews. Harkin HEA Reauthorization Discussion Draft (June 25, 2014), Sec. 498A(b)(3), <http://www.help.senate.gov/imo/media/doc/HEAA%20Discussion%20Draft%20Language%206.25.14.pdf>.

⁷⁰ HEA § 498A, 20 U.S.C. § 1099c; see also Federal Student Aid, Program Review Guide for Institutions (2009), <http://www.ifap.ed.gov/programrevguide/attachments/2009ProgramReviewGuide.pdf>

- *Potential benefits.* The program review function is an important accountability tool controlled by ED, but it is currently used in a way that is opaque and not clearly defined in terms of risk. Creating a clear definition of risk and prioritizing certain factors may be a way for this accountability tool to be used in a more meaningful, transparent way. Systems also might be designed in a way to complement activity by other members of the triad; if accreditors were also using risk-informed regimes, for example, the risk factors and consequences between those regimes and ED's program reviews may make for more effective and aligned overall accountability systems.
- *Potential challenges.* ED has limited resources to conduct program reviews, and the risk factors for program reviews should not be so broad as to implicate more institutions than ED can effectively review in a single year. (Senator Harkin's bill, for example, has been estimated to implicate thousands of institutions per year—a number far beyond FSA's current capacity.⁷¹) And program reviews can be a significant burden for institutions undergoing them; any risk-informed systems must be developed in a way that complements (rather than duplicates) efforts by other regulatory bodies and regulatory partners (i.e., states and accreditors).

V. CONCLUSION

While certain areas within the HEA may be ripe for exploration of new risk-informed regimes, others simply are unlikely to be appropriate or ready for such pursuits. As policymakers explore the adoption of new risk-informed regimes, they should take care to balance the burdens and expected benefits of these new regimes within the overall context of the importance of effectively regulating a sector that receives billions of dollars in taxpayer and student dollars every year. Creating a system that supports deterministic and risk-informed regimes is entirely possible—but care must be taken not to create greater burdens by layering new regulatory approaches on top of existing requirements, nor to abandon critical protections of student and taxpayer investments.

Moreover, policymakers must be clear on the goal of creating new risk-informed regimes. Is the intention that an entire area of regulation be replaced by a new risk-informed regime? Or should some parts of the regime remain deterministic while others become risk-informed? Should the new approach apply to all institutions? Or should the risk-informed regime be applied only to a subset of institutions (at least as a pilot for the initial period of implementation)? Though the latter approach may provide an opportunity for less complexity and controversy at the outset, it may also create a regulatory environment that is even more complex and confusing than what we have today. A primary interest should be to do no harm.

The current policy environment requires ED to develop strategies for using its resources effectively and efficiently—particularly to allow for better responsiveness to the unique circumstances presented by different institutions in various regulatory contexts. ED's efforts should be targeted at the areas most in need of federal oversight and enforcement, in light of a realistic assessment of capacity and expertise. Federal resources should not be spread so thin that enforcement mechanisms are ineffective and regulatory requirements impose burden on institutions often without real impact (particularly when compliance burdens siphon institutional resources away from functions essential to student success). Risk-informed regimes hold significant promise to aid in this effort, but ED may need additional capacity with new skill sets to ensure these new regimes are effective.

So what's next? First, the higher education community should come together to identify the most viable regula-

⁷¹ Molly Corbett Broad, Letter on the Harkin Higher Education Act Reauthorization Discussion Draft 3 (Aug. 29, 2014), <http://www.acenet.edu/news-room/Pages/Letter-on-the-Harkin-Higher-Education-Act-Reauthorization-Discussion-Draft.aspx>.

tory area(s) for new risk-informed regimes. Additional papers should explore which areas are most ripe and lay out design options. A commission, task force, or other body made up of a variety of stakeholders—in collaboration with ED and Congress—may be an appropriate body to decide on the best areas to determine risk-informed approaches, design specific systems, and make recommendations on key decisions about metrics, thresholds, and regulatory response strategies. Congress may want to hold hearings to understand the ripeness, fit, and impact of implementing risk-informed regimes in various areas of higher education regulation. And, in the meantime, ED can assess where it might make changes without legislation and explore whether there is a more effective regulatory strategy that could be deployed within its existing authority. The potential payoff of a well-designed risk-informed regime to create more effective regulation is significant enough to merit the pursuit of these important steps.

Questions on the Horizon

This paper is intended to be an important early step in a long-term conversation about the prospect for the incorporation of risk-informed regimes within the regulatory system for institutions of higher education. Some important questions include:

1. Within the full range of federal regulations of higher education (at least within the context of compliance with federal financial aid programs in Title IV), what areas may be ripe for risk-informed regulation—and what areas are not?
2. What should institutions and regulators expect in terms of initial investments and long-term benefits? For example, would the adoption of risk-informed regimes truly lead to meaningful lower burdens for high performers with low risk?
3. Would the adoption of risk-informed regimes help ED (and other regulatory partners such as accrediting agencies) allocate their enforcement resources more accurately?
4. In the context of institutional quality, what metrics should factor into a risk assessment, how should thresholds be determined, and who is responsible for making these decisions?
5. How can Congress, ED, and other stakeholders be able to trust one another to design, carry out, and comply with risk-informed regimes, particularly when these regimes require removing other requirements or safeguards?

APPENDIX A: RISK-INFORMED PROCESS MAP

The following table aligns with the guiding principles for the design, implementation, and continuous improvement of risk-informed regimes in Education Counsel’s 2014 white paper, *New Directions in Regulatory Reform: Prospects for Reducing Regulatory Burden Through Risk-Informed Approaches in Federal Law Governing American Higher Education*. This appendix is intended to serve as a standalone resource that may be used to inform future discussions among policymakers and stakeholders about new regimes to explore.

Process step	Key concepts	Potential key questions
Necessary prerequisite conditions	<p>A risk-informed regulatory regime should only involve areas where regulators have clear authority to develop a risk-informed regime or significant discretion in determining regulatory response. Granting accrediting agencies flexibility to establish risk-informed review procedures (as explored in more detail later in the paper) is likely to be an appropriate area, while using a risk-informed system to enforce federal civil rights laws is not, given the legally mandated statutory and constitutional rights and protections associated with individual student rights that dictate permissible regulatory parameters.</p> <p>Risk should be defined very precisely and concretely. The examples of successful risk-based and risk-informed systems described above started first with the question of the risk or danger to be avoided (e.g., cancer rates for nuclear power plants), and built the system from there.</p> <p>The regulatory area should have some type of <i>prospective</i> risk involved.</p> <p>The regulatory area should implicate a risk that is measurable through existing data sources.</p> <p>There should be some evidence that regulated entities are likely to fall under each level of risk defined. In other words, the risk thresholds should relate to known variances in performance related to the risk in question, even though the precise lines between thresholds should not be drawn at the outset.</p> <p>Regulators should be able to develop a range of potential regulatory responses that are specifically tailored to the different levels of identified risk. This process likely provides an opportunity for regulators to be more systematic and strategic in how they allot technical assistance, make requests for additional information, and impose more severe consequences.</p>	<p>Is the risk in question real and easily understood? Does it implicate a specific area of regulation?</p> <p>Do the likely benefits of the prospective risk-informed regime outweigh the likely challenges (both in the short and long term)?</p> <p>Does stakeholder support exist for the concept of shifting to a risk-informed regime <i>and</i> are stakeholders committed to the hard work of turning the concept into an actual regulatory regime?</p>

Process step	Key concepts	Potential key questions
System design	<p>The system should incorporate the five key functions present in mature regimes:</p> <p>Defining the purpose and goals of the system in terms of specific risks</p> <p>Determining the responsible agency or organization’s own risk appetite</p> <p>Assessing the risk and its likelihood of occurrence</p> <p>Assigning scores or ratings to regulated entities on the basis of risk assessments</p> <p>Linking regulatory responses and resources to scores or ratings categories (for individual regulated entities and/ or for system-wide issues)</p> <p>The type of risk in question and the different thresholds for performance should be clearly defined by regulators (and, in some cases, enforcement partners such as accrediting agencies), with the input of the full range of stakeholders.</p> <p>Data and information sources to determine and monitor risk should be clearly defined before any assessment of risk takes place.</p> <p>Thresholds should be based on accessible and reliable data and information sources—and collection should be based on existing sources and through existing collection methods wherever possible to avoid duplication of existing reporting requirements.</p> <p>Regulatory responses should be tiered and should be defined in direct relation to the types of risk that they are intended to address.</p> <p>If systems are defined as “opt in” by institutions, every effort should be made to avoid the creation of multiple regulatory regimes that may conflict or overlap with one another.</p> <p>Regulated entities and other stakeholders should be given multiple opportunities to contribute to and comment on the proposed system design elements.</p>	<p>What body is the most efficient and effective entity to maintain oversight or control over the contemplated risk informed regime?</p> <p>What are the risk variables at the top of the hierarchy? Are the metrics that are incorporated into the risk determination primarily outcome measures that related directly to the defined risk areas for the regime?</p> <p>Do proposed metrics and thresholds appropriately allow for differences in institutional mission and students served? Are all institutions implicated by the regime responsible under similar performance standards that may nevertheless be applied by regulators in a way that appropriately accounts for different contexts?</p> <p>Who should be responsible for defining the risk and identifying appropriate metrics and thresholds? And based on what process?</p>

Process step	Key concepts	Potential key questions
System implementation	<p>The primary oversight body and enforcer of the new risk-informed regime should be prepared for an initial investment of time and resources to set up the regime, to provide information and technical assistance, and to conduct a baseline assessment for regulated institutions. Regulated institutions will also need to invest resources into understanding and complying with the new requirements.</p> <p>Piloting of the system for a small number of regulated entities may be an important foundation for informing how risk is defined and assessed over time. No binding regulatory response should take place for at least the early phase of the pilot.</p> <p>Regulated entities and other stakeholders should be given multiple opportunities to comment on the implementation process to inform final processes and system elements.</p>	<p>Are all system participants prepared for the initial investment of time, effort, and resources – and clear about the longer-term payoff for this investment?</p> <p>Are regulators prepared and empowered to make mid-course corrections when problems arise?</p>
System evaluation and improvement	<p>Regulators should regularly review overall system performance, with special attention to tracking how institutions are categorized on the basis of risk and what types of regulatory responses are most common. Adjustments should be made as appropriate.</p> <p>Regulatory burden should also be regularly assessed, both for regulated institutions and for regulators. Adjustments should be made as appropriate.</p> <p>The definition of risk, how it is assessed, and how regulators respond should be regularly revisited and revised.</p>	<p>How can the regime mitigate unanticipated, unforeseen, or misunderstood elements of the definition of risk, the identified thresholds and metrics, and the appropriate regulatory responses?</p> <p>Does the regime tend to affect certain types of institutions in unique ways? Are any institutions experiencing negative consequences due to student demographics and other factors outside the institutions' control?</p> <p>How can best practices and lessons learned be memorialized and shared?</p>

APPENDIX B: RECOMMENDED READING ON RISK-INFORMED REGIMES

General information about risk-informed models and design theory:

- Julia Black and Robert Baldwin, *Really Responsive Risk-Based Regulation*, 32 Law & Policy 181, 184–85 (2010)
- Jonathan Coburn and Greg Weddle, *Risk-Based Regulation: Learning from the Experience of Others*, Bio-Process Int'l 22-23 (Sept. 2006)
- Peter May, Performance-Based Regulation, Jerusalem Papers in Regulation & Governance Working Paper No. 2 (April 2010), <http://regulation.huji.ac.il/papers/jp2.pdf>
- William D. Travers, Risk-Informed and Performance-Based Regulation (March 1, 1999), <http://www.nrc.gov/reading-rm/doc-collections/commission/srm/1998/1998-144srm.pdf>

U.S. models in other sectors:

- Basel Committee on Banking Supervision, Basel III: A global regulatory framework for more resilient banks and banking systems (rev. June 2011), www.bis.org/publ/bcbs189.pdf
- Food & Drug Administration, Federal Communications Commission, and Office of the National Coordinator for Health Information Technology, FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework (April 2014), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf>

Australian and U.K. models in postsecondary regulation, including technical information about metrics, thresholds, and methods of calculation:

- Australian Government Tertiary Education Quality and Standards Agency, TEQSA Annual Report 2013–14 (tabled in Parliament Oct. 24, 2014), http://www.teqsa.gov.au/sites/default/files/publication-documents/TEQSA2014AnnualReport_FullReportWeb.pdf
- HEFCE, Memorandum of assurance and accountability between HEFCE and institutions: Terms and conditions for payment of HEFCE grants to higher education institutions (June 2014), http://www.hefce.ac.uk/media/hefce/content/pubs/2014/201412/HEFCE2014_12.pdf