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Upcoming Events

Conferences:

Lab Leadership Summit: Designing, Implementing & Managing a High-Profit Lab Outreach Program
May 11, 2017 – 8 a.m.-5 p.m.
Holiday Inn Airport South, Atlanta, GA
www.lableadershipsummit.com

Lab Institute 2017
October 25-27
Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

Trump Budget "Blueprint" Proposes NIH Cuts, Increases for FDA User Fees and Enforcement

The headlines are harsh. "Terrible," devastating," and "crippling," are words the biomedical industry is using to describe President Trump's proposed cuts to science and medical research in his 2018 budget proposal. On the flip side, some increased funding targets enforcement and public health.

While only Congress has the authority to make budget and appropriation decisions, the administration's budget is considered a "blueprint" of the president's spending priorities. Experts say based on the deep cuts in the 2018 budget proposal to the U.S. Department of Health and Human Services (HHS), including the National Institutes of Health (NIH), biomedical funding is clearly not a priority for Pres-

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Industry Claims New Wellness Program Bill Threatens Privacy of Genetic Testing Information

A new bill promoted as supporting workplace wellness programs has met with significant backlash, criticized as forcing employees to give their employers genetic testing results. The proposed bill, "Preserving Employee Wellness Programs Act," states its purpose is to "clarify rules relating to nondiscriminatory workplace wellness programs." The Committee on Education and the Workforce, whose chair Representative Virginia Foxx (R-North Carolina) sponsored the bill, explains the legislation responds to EEOC actions that restricted employers' ability to offer incentives to employees participating in wellness programs.

What the Bill Says

The bill stipulates that "collection of information about the manifested disease or disorder of a family member shall not be considered an unlawful acquisition of genetic information with respect to another family member as part of a workplace wellness program offered by an employer and won't violate the Genetic Information

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Trump Budget "Blueprint" Proposes NIH Cuts, *from page 1*

ident Trump. In his introductory message to the budget proposal President Trump explained that "defense and public safety" budget increases would be offset by "finding greater savings and efficiencies across the Federal Government. ... We are going to do more with less, and make the Government lean and accountable to the people."

"The Trump administration's proposed budget would cripple the science and technology enterprise through short-sighted cuts to discovery science programs and critical mission agencies alike," said Rush Holt, CEO of the American Association for the Advancement of Science in a statement. "Investments in federal research and development make significant contributions to economic growth and public well-being. The administration's proposed cuts would threaten our nation's ability to advance cures for disease, maintain our technological leadership, ensure a more prosperous energy future, and train the next generation of scientists and innovators."

The diagnostics industry would be impacted by both the proposed cuts to the NIH, as well as the increase in U.S. Food and Drug Administration (FDA) user fees proposed in the budget. Also subject to increase is funding for enforcement efforts, particularly the Health Care Fraud and Abuse Control Program (HCFAC).

NIH Budget Cuts

In the proposal, $69 billion is requested for HHS, a $15.1 billion decrease (or 17.9 percent) from the current level. The NIH stands to lose $5.8 billion (an almost 20 percent reduction), bringing its funding to $25.9 billion, which is below 2003 levels. By comparison, 2013 sequestration cuts cut the NIH budget by 5 percent, a fraction of what's being proposed by the Trump administration. Even still, sequestration, the institute said, led to 700 fewer competitive research grants in fiscal year 2013.

"In the last 15 years, NIH-funded research has built the foundation for many of America's biotechnologies, such as developments in cancer treatments, genomics, and medical diagnostics," said Darrell Kirch, M.D., president of the Association of American Medical Colleges, in a statement. "Medical research takes years to translate from the bench to the bedside and cannot be turned on and off like a faucet. The proposed cuts would set back progress toward critical advancements that could take decades to regain, prevent new ideas from being explored, and have a chilling effect on those who would potentially enter the biomedical research workforce."

The Trump administration says the budget proposal "reduces administrative costs and rebalance[s] Federal contributions to research funding." While details are scarce in the two pages dedicated to HHS, the budget proposal also mentions "a major reorganization of NIH's Institutes and Centers."

Advocates for science and medical research remain hopeful that Congress will maintain its bipartisan history of "protecting" research investments, as Congressional members from both parties have expressed public concern over the proposed NIH cuts.

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— Darrell Kirch, M.D.

FDA User Fees

In addition to the proposed cuts to NIH funding levels, the administration's proposal looks to "recalibrate" medical product user fees, which could double what pharmaceutical companies and medical device manufacturers (including diagnostics companies) would pay in review costs. The FDA had decreased user frees in 2017 to what the Regulatory Affairs Professionals Society says are the lowest fees since 2013. The White House says the proposed increase in fees is "designed to achieve regulatory efficiency and speed." However, given the current shortage of FDA reviewers and the federal hiring freeze, experts are skeptical the increase in fees would achieve its stated goal.

HCFAC Increases

One area receiving a budget increase rather than cuts is Medicare and Medicaid fraud enforcement. The Blueprint includes a commitment to "investing in activities to prevent fraud, waste, and abuse and promote high quality and efficient health care." Recognizing that "[a]dditional funding for the Health Care Fraud and Abuse Control (HCFAC) program has allowed the Centers for Medicare & Medicaid Services in recent years to shift away from a "pay-and-chase" model toward identifying and preventing fraudulent or improper payments from being paid in the first place," the budget raises HCFAC discretionary funding for 2018 by $70 million to $751 million.

Public Health Emergency Funding

The proposed Budget also "[r]eforms key public health, emergency preparedness, and prevention programs"—such as changing preparedness grants to "reduce overlap," save expense and channel funding to states most in need. Additionally, the budget calls for a new Federal Emergency Response Fund to address public health crises such as the Zika Virus outbreak. Finally, the Centers for Disease Control and Prevention would get a $500 million block grant designed to provide more flexibility and address state-specific needs.

Takeaway: If enacted, the Trump administration cuts to the NIH could have profound negative effects on biomedical research and would increase FDA user fees. While Congress will ultimately decide the budget, the White House proposal would be detrimental to the biomedical industry, including the diagnostics sector.

OIG and DOJ Provide Tips for Determining Effectiveness of Compliance Programs

Labs have two new compliance tools—from the Department of Justice (DOJ) and the Office of Inspector General (OIG)—focused on evaluating the effectiveness of compliance programs. The DOJ's resource addresses evaluation of a compliance program in the context of fraud prosecution while the OIG's tool has a more proactive objective, to measure programs periodically, even when no misconduct or investigation is at issue.

Both the OIG and DOJ caution that these resources are not "one-size-fits-all," nor are they meant to be a checklist or standard formula rigidly applied, but instead the elements discussed should be applied on a case-by-case basis. Both resources share similar themes and concerns and demonstrate a faithfulness to the core principles of effective compliance programs first discussed nearly 20 years ago in the OIG's Compliance Program Guidance for Clinical Laboratories.

The *"intent of this exercise was to provide a large number of ideas for measuring the various elements of a compliance program."*

Here's a summary of some key takeaways from each of these compliance resources.

OIG/HCCA Resource Guide

The OIG collaborated with the Health Care Compliance Association to produce a Resource Guide to help organizations evaluate the effectiveness of their compliance programs. This is the latest collaboration with the HCCA aimed at providing compliance assistance to the health care industry. Two years ago, they collaborated on guidance for boards of directors to assist in ensuring proper oversight of compliance programs. See "OIG & Industry Leaders Collaborate on Guidance Regarding Compliance Oversight" May 1, 2015.

The current Resource Guide is the fruits of a HCCA- OIG Compliance Effectiveness Roundtable held in January 2017 in Washington DC. The roundtable involved compliance professionals, Department of Health and Human Services and Office of Inspector General staff. The "intent of this exercise was to provide a large number of ideas for measuring the various elements of a compliance program," the OIG said in the Guide's introduction. The result was a list that offers "measurement options to a wide range of organizations with diverse size, operational complexity, industry sectors, resources, and compliance programs."

The Guide is organized around seven categories taken from the HCCA's *CHC Candidate Handbook: Detailed Content Outline*. Within these categories the Guide discusses what and how to measure a compliance program's effectiveness, suggesting steps to take in evaluating the program. Those seven categories are:

1. **Standards, Policies and Procedures**—The Guide suggests periodically reviewing these compliance resources, ensuring they are updated, accessible to and understood by employees and enforced by the administration.

The DOJ said it doesn't "use any rigid formula to assess the effectiveness of corporate compliance programs" and instead makes "individualized determination[s]."

2. **Compliance Program Administration**—Organizations should assure there's adequate staffing and budget for compliance; review oversight committee's goals and functions; verify role and authority of compliance officer, counsel, compliance committee and the governing board and review organizational structure; ensure development of risk assessment plans, internal controls, periodic compliance program reviews and annual compliance work plan.
3. **Screening and Evaluation of Employees, Physicians, Vendors and other Agents**—Ensure job descriptions and performance evaluations include compliance element, verify processes to identify conflicts of interest and background checks of staff and appropriate due diligence for third parties.
4. **Communication, Education, and Training on Compliance Issues**—Make sure compliance updates are communicated throughout the organization and regular training and continuing education is provided and participation tracked.
5. **Monitoring, Auditing, and Internal Reporting Systems**—Develop audit plans and internal reporting mechanisms and measure accessibility and effectiveness, assure that regular monitoring and auditing is performed, verify risks identified in such activities or through internal reporting are responded to/addressed in timely manner and retaliation is not occurring, and review corrective action activities.
6. **Discipline for Non-Compliance**—Ensure consistent and proportionate disciplinary action taken and properly documented.
7. **Investigations and Remedial Measures**—Review corrective action to ensure noncompliance appropriately handled, investigations properly conducted and documented, remedial action taken to prevent future risk, organization appropriately cooperates with government entities, and overpayments are timely refunded.

DOJ Evaluation of Compliance Programs

The DOJ also released a document titled Evaluation of Corporate Compliance Programs discussing the effectiveness of compliance programs—which is one of the so-called "Filip Factors" that federal prosecutors use when considering prosecution of a business. The document instructs that prosecutors consider those factors "in conducting an investigation of a corporate entity, determining whether to bring charges, and negotiating plea or other agreements."

The DOJ said it doesn't "use any rigid formula to assess the effectiveness of corporate compliance programs" and instead makes "individualized determination[s]." However, there are "common questions" to be asked about compliance programs and this new document "provides some important topics and sample questions that the Fraud Section has frequently found relevant in evaluating a corporate compliance program." The document's topics and questions are also described as related to topics in the US Sentencing Guidelines and other criminal prosecution/fraud section guidance documents.

The document addresses 11 topics with specific questions to ask under each topic. The DOJ notes that not every question will be applicable in every case and this isn't a checklist or a formula. However, these topics and questions provide valuable insight for organizations to use in proactively evaluating the effectiveness of their compliance programs. Here are some takeaways gleaned from a review of the document's 11 topics and related questions:

1. **Analysis and remediation of misconduct:** The government is concerned with whether organizations seek to find the root cause of misconduct and whether systemic issues were involved. Additionally, it's important to consider whether the misconduct could have been prevented, whether the company shouldn't have known about the misconduct due to audits, internal reporting or investigations and if so, why it wasn't caught earlier. Most importantly, what does the company plan to do after the misconduct is discovered—how will it make sure it doesn't happen again?
2. **Management:** Following the often-discussed "tone-at-the-top" theme, the document focuses on whether senior leaders "encouraged or discouraged" misconduct and "modelled proper behavior." How does leadership communicate a commitment to compliance? The board of directors' resources and access to compliance expertise, use of eternal auditors, communication with compliance team and their oversight activities are all key concerns.
3. **Compliance resources and autonomy of compliance personnel:** How does the company value its compliance functions? Does a company pay as much attention and devote the resources to compliance activities and the compliance team as it does to other functions? The government is also concerned about whether resources are commensurate with risk of the organization and whether compliance team requests for resources have been met. The importance of compliance to "strategic and operational decisions" is also analyzed. The questions asked reinforce guidance included in other compliance resources that recommend the compliance team have direct reporting capability to the board of directors, meet directly with the board and have independence so they can adequately perform their function without influence from management. The questions probe whether compliance functions have reported concerns, and whether deals or transactions have been stopped or changed due to compliance team's expressed concerns.
4. **Policies and procedures:** The document's questions emphasize the need for policies and procedures that can prevent misconduct and proper communication of these to employees, as well training and oversight of implementation.
5. **Risk assessment:** The questions focus on methods the company uses for detecting risks and misconduct.
6. **Training and communication:** The document expresses government concern about how well-tailored training is to employees based on their roles and risk level and how well the training is designed to be understood and effective.

7. **Reporting and investigation measures:** Relating back to initial topics on risk analysis and investigation, the government is concerned about how well entities collect and use information from compliance reporting resources and whether reports are taken seriously, how an entity responds to compliance reports and investigates reports or actual misconduct, including "[h]ow high up in the company … investigative findings go."
8. **Discipline and incentives:** Compliance programs should incentivize compliance and appropriately discipline non-compliance, including holding managers and supervisors accountable for allowing misconduct to occur.
9. **Continuous improvement:** This section focuses on internal audits, control testing and updated risk assessments, policies and procedures.
10. **Use of third party management entities:** The questions on this topic focus on why companies outsource functions, how they control the relationship with and conduct of the third party and whether due diligence is performed and third party conduct is monitored and disciplined when necessary.
11. **Compliance in merger and acquisition scenarios:** Due diligence is also a key concern in the last item regarding arrangements with other entities and whether such due diligence identifies risk of misconduct. Additionally, companies need to be concerned about how well they integrate compliance into the resulting entities.

Takeaway: Laboratories can benefit from two new compliance tools to evaluate their compliance programs and ensure their effectiveness.

Executive Orders Move Forward Regulatory Reform Plans

At the end of February, President Donald Trump issued an Executive Order (EO) aimed at furthering the promise to reduce regulatory burdens and costs. The President's Blueprint for the budget, which discussed the executive order, declared "[a]s a successful businessman, the President knows that achievement requires accountability." Therefore, he issued this latest EO to require regulatory agencies each appoint a regulatory reform officer (RRO) and set up regulatory reform task forces (RRTFs).

These steps will facilitate the Jan. 30th Executive Order 13771, which called for paring down federal regulations. EO 13771 requires that for every new regulation proposed, two existing regulations must be eliminated (aka "one in, two out").

The agencies must designate RROs within 60 days of the order. The RRO is charged with:

- Overseeing regulatory reform efforts such as those required by the one-in, two-out EO

- Oversee planning and review, including retrospective review and termination of regulations and attendant programs and activities.
- Periodically report to the agency head and consult with other agency leaders
- Participate in and even possibly chair the RRTF.

The Budget notes that in support of accountability "these teams will be a critical means by which Federal agencies will identify and cut regulations in a smart and efficient manner."

As to implementation, the EO states the "RRTF will include the RRO, the agency's regulatory policy officer, representation from the agency's central policy or similar office, and at least three senior agency officials. The RRTF must review existing regulations and recommend those needing "repeal, replacement, or modification." Such regulations should be those that adversely affect new and existing jobs; are "outdated, unnecessary, or ineffective;" generate "costs that exceed benefits"; are inconsistent or interfere with regulatory reforms.

Stakeholders such as state and local governments, trade associations, businesses and consumers should be permitted to have input on these regulatory reform efforts. Within 90 days of the order the RRTF has to provide an initial report to the agency head regarding it's efforts to identify regulations for "repeal, replacement or modification."

Congress Proposes New Legislation Addressing LDTs

The House of Representatives took steps to initiate reform with regard to laboratory developed tests with the proposed Diagnostic Accuracy and Innovation Act, which calls for creation of a new regulatory category for *in vitro* clinical tests (IVCTs) distinct from medical devices. It would include both finished products (such as kits and test platforms) and laboratory test protocols commonly referred to as LDTs.

Regulatory authority over IVCTs would be shared between the FDA and CMS. The FDA would oversee "design, development, and validation of an IVCT as well as the production of an IVCT for distribution to another facility or third-party." CMS, under a modernized CLIA, would have jurisdiction of "all the activities necessary to perform or 'run' a developed IVCT, including the preparation of reagents for use in a single CLIA facility, sample preparation, and other pre-analytical processes." Finally, medical use of IVCT and interpretation of results would be left to the states for governance as the practice of medicine.

CMS, OIG Reps Address PAMA, Fraud Enforcement at ACLA Annual Meeting

At the American Clinical Laboratory Association annual meeting in Washington, D.C. March 23, representatives of the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) provided insight on current challenges facing laboratories.

Carol Blackford, Director, Hospital and Ambulatory Policy Group of CMS reported on current implementation of the Protecting Access to Medicare Act (PAMA) and mentioned the agency has received requests for an extension of the March 31 reporting deadline under PAMA. She was unable to say at that time whether a delay in that deadline would happen. However, CMS announced as we went to press that it would exercise enforcement discretion until May 30 (see box).

Senior Counsel Karen Glassman of the U.S. Department of Human Services OIG highlighted recent enforcement efforts and noted common fraud theories applicable for laboratories include billing for tests not ordered or performed, improper CPT and diagnosis coding, lack of medical necessity and Stark and Anti-Kickback violations. Among the latest fraud trends she discussed were marketing arrangements, genetic testing scams and medical necessity issues.

Glassman also discussed the collaborative nature of enforcement, with federal agencies cross referring cases and findings of their reports and investigations. While reviewing recent settlements and enforcement cases in the laboratory sector and the compliance issues at the heart of those cases, she emphasized the OIG's focus on individual accountability. In response to a question about the future of individual responsibility under the Yates memo now that Sally Yates is no longer deputy attorney general, Glassman responded that she couldn't speak for the DOJ (the agency that released the Yates memo) but that the Yates memo "only reiterated what [the OIG's] focus has been for a long time." She also indicated that OIG focus on holding individuals responsible was likely to continue.

Finally, Glassman ended with some compliance tips for laboratories: Treat compliance as a team sport, involving all areas of the organization, use compliance metrics and include compliance in employee performance reviews to provide compliance incentives, stay up-to-date with OIG publications and guidance such as the Work plan that indicate the areas it is concerned about and evaluate the organization's risks.

Takeaway: Labs face significant compliance and reimbursement challenges and government agencies seek to provide resources to help.

CMS Delays Enforcement of PAMA Reporting Deadline

Responding to pleas from the industry, the Centers for Medicare & Medicaid Services announced on March 30, 2017 that it will exercise "enforcement discretion" until May 30, 2017, and wouldn't impose potential civil monetary penalties for failure to report applicable information under PAMA before that date. That relief comes just in time before the March 31 data reporting period deadline. CMS added that the 60-day enforcement discretion "is the maximum amount of time CMS can permit to still have sufficient time to calculate the CLFS payment rates scheduled to go into effect on January 1, 2018."

Industry Claims New Wellness Program Bill Threatens Privacy, *from page 1*

Nondiscrimination Act of 2008" (GINA). Family member is intended to have the same meaning as it does in GINA.

That provision regarding information collection is being challenged within the diagnostics industry as threatening privacy rights—specifically with regard to genetic testing information. Earlier this month, the American Society of Human Genetics (ASHG) expressed its opposition to this bill claiming it will "fundamentally undermine the privacy provisions of the Genetic Information Nondiscrimination Act (GINA) and the Americans with Disabilities Act (ADA)."

"Americans must be able to continue to volunteer for research and benefit from genetics-based clinical advances without fear of workplace discrimination based on its findings"

— Nancy J. Cox, PhD

What's at Stake

Supporters of the bill argue that this bill is needed to make clear that financial incentives can be awarded to those employees who agree to participate in wellness programs, without violating anti-discrimination laws such as ADA and GINA. A Committee on Education and the Workforce fact sheet promoting the bill refers to a discount of 30 percent of premiums as a permissible incentive to encourage employees to participate rather than a penalty for failure to participate.

But opponents take the opposite view claiming that voluntary plans can become mandatory for employees and assert that the 30 percent premium difference is a surcharge. The EEOC challenged employer wellness programs in recent years arguing the incentives for participating or penalties for not participating can make the programs mandatory rather than voluntary. In fact, as the *New York Times* reported last fall, an AARP lawsuit against the EEOC "questions whether the programs are truly voluntary when the price of not participating can be high"—i.e., 30 percent of health insurance premiums. That lawsuit followed the EEOC's issuance of two final rules addressing the ADA and GINA to address the wellness program incentives. Those rules went into effect this year.

ASHG emphasizes that the ADA and GINA protect employees from sharing genetic or other "sensitive" health information with employers and calls for genetic information involved in workplace wellness programs to only be shared with health care professionals. The new bill ASHG argues "would effectively repeal these protections by allowing employers to ask employees invasive questions about their and their families' health, including genetic tests they, their spouse, and their children may have undergone."

"Americans must be able to continue to volunteer for research and benefit from genetics-based clinical advances without fear of workplace discrimination based on its findings," said ASHG president Nancy J. Cox, PhD in a statement.

Takeaway: While precision medicine is touted as the future of health care and reforms aim to promote wellness and innovative ways to keep patients healthy, a bill purported to further that mission raises debate about genetic testing information and privacy.

UPDATE: Latest Changes to Trump Travel Ban

While it is currently blocked from being enforced by orders from federal courts in Hawaii and Maryland (as we went to press), it's still important to keep an eye on the Executive Order containing President Trump's revised travel ban. Last month, we outlined the major effects of the first order (See *NIR* Feb. 2017). Much of the new version looks familiar but it does include a few key changes that you need to know about. Here's a quick rundown including a side-by-side comparison.

1. 10-Day Grace Period

The previous executive order took effect immediately on the date it was issued, Jan. 27, 2017. Without notice or time to respond, many visa holders were left stranded abroad. The new order was to take effect on March 16, 2017, 10 days after it was issued, and exempts current visa holders.

2. Iraq No Longer on Restricted Countries List

Unlike the old version which covered seven countries—Iran, Iraq, Libya, Somalia, Sudan, Syria and Yemen—the new version omits Iraq.

At A Glance: The Differences between the New & Original Travel Ban

Provision	Original Ban	New Ban
Effective Date	Took effect immediately	Takes effect after 10-day grace period (March 16)
Restricted Countries	Iran, Iraq, Libya, Somalia, Sudan, Syria, Yemen	Iran, Libya, Somalia, Sudan, Syria, Yemen (Iraq removed)
Duration of Restrictions on Syrians	Indefinite	Same as other restricted countries, i.e., 90 day travel, 120 day refugee
Impact on Green Card Holders	Covered	Exempt
Impact on Dual Citizens	Covered	Exempt
Pre-Existing Refugee Status	Covered	Exempt
Individual Exemptions	Granted case-by-case without specific process or standards	Waivers to be granted via formal process, which isn't described
Religious Preferences for Post-Ban Refugees	Priority for Christians in Muslim countries	None expressed

3. Elimination of Extra Restrictions on Syrians

Previously, the order imposed three different entry bans, based on nationality and entrant status with Syria having an indefinite ban. That indefinite ban on Syrians has been removed and the new order treats Syrians the same as the other restricted nationalities:

Duration	Entrant Status	Entrant Nationality
90 days	Travelers	Iran, Libya, Somalia, Sudan, Syria, Yemen
120 days	Refugees	All nationalities (exemption for refugees granted status or scheduled for transit into US before March 16)

4. Exemption for Green Card Holders

The old order lacked some clarity with regard to the impact on green card holders. A Department of Homeland Security press release referred to case-by-case determinations leaving it open that a green card holder could be barred entry if there was evidence that the individual posed a serious threat. The new order makes a clear exemption for green card holders and persons with valid visas.

5. Exemption for Dual Citizens

The prior order covered dual citizens of both a restricted and non-restricted country outside the US, including a US ally like the UK, Canada, Australia

or Germany. However, the new order includes a clear exemption for citizens of restricted countries who are dual citizens of a non-restricted country.

6. Exemption for Previously Granted Refugee Status

Previously, the 120-day travel ban into the US included no exemptions. But, the new version states that the 120-day travel ban does not apply to individuals formally granted refugee status or scheduled for transit to the US by the State Department before the order's effective date.

7. Individual Exemption Process

Previously, the order would allow the DHS and State Department to grant individual exemptions on a "case-by-case" basis. The courts said the provision violated "due process" because it didn't establish clear standards or processes. Now, the wording hints that there will be a formal process for banned individuals to apply for a "waiver" but doesn't list specifics.

8. Elimination of Post-Ban Religious Preferences

Upon restoring refugee entry after the ban, the prior order directed the DHS and State Department to give priority to refugees claiming religious persecution, "provided that the religion of the individual is a minority religion in the individual's country of nationality."

The current version eliminates the controversial "religious test" language which was criticized as expressing preference for Christians in Muslim countries.