

Response to request for information:
AHCA RFI 003-18/19
Canadian Prescription Drug
Importation Program

Agency for Health Care Administration

June 25, 2019

Redacted



Building a better
working world



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Crystal Demott
Agency for Health Care Administration
Solicitation.questions@ahca.myflorida.com

June 25, 2019

Dear Crystal,

On behalf of Ernst & Young LLP (EY US), we are pleased to respond to your Request for Information (RFI) for the Canadian Prescription Drug Importation Program, AHCA RFI 003-18/19.

We recognize this initiative is of the highest priority for AHCA and the State of Florida. We would welcome the opportunity to help the Agency think through the right questions to ask as a plan is developed for a successful implementation and operation of this new endeavor. Within the accompanying response, we have introduced many elements that we believe should be part of thought provoking discussions during this critical planning stage, and encourage AHCA leadership to engage in follow up dialogue with all qualified responders to this RFI.

Through our response details, AHCA leaders will gain an understanding of EY capabilities specifically designed to successfully support this type of initiative. EY has a strong history supporting Government Public Sector (GPS) clients (including state & local agencies, municipalities, provincial and federal governments) within Florida, across the US and Canada, and internationally. Highlights of the value EY will bring to AHCA:

- ▶ EY has a significant amount of experience working with the regulatory, compliance and supply chain aspects of the Canadian and US Pharmaceutical industry at large. In developing this response, we worked with our Canadian Health and Life Sciences Advisory leader, Giselle Commissiong. Her direct experience and insights offered in this response are representative of our understanding of AHCA's needs and will be complimented by a talented US team of individuals who understand how to plan, design and operationalize a program of this nature.
- ▶ To provide the least amount of unnecessary risk to this initiative, AHCA leadership can count on EY to bring an established understanding of how the Canadian pharmaceutical market is designed and operates, how the State of Florida ecosystem is designed and operates in order to successfully work across the agencies when necessary to accomplish large goals, and ultimately bring the two cross border entities together for ultimate success.
- ▶ For alignment with the Florida Medicaid program environment, we will leverage a network of highly skilled professionals from our GPS advisory practice which is dedicated to serving local government and public sector organizations. We combine a wealth of consulting capabilities – strategy, customer, finance, IT, supply chain, people and organizational change, program management and risk – with a comprehensive understanding of AHCA's most complex issues and opportunities, and blend it with pharmaceutical subject matter expertise we offer within the firm.

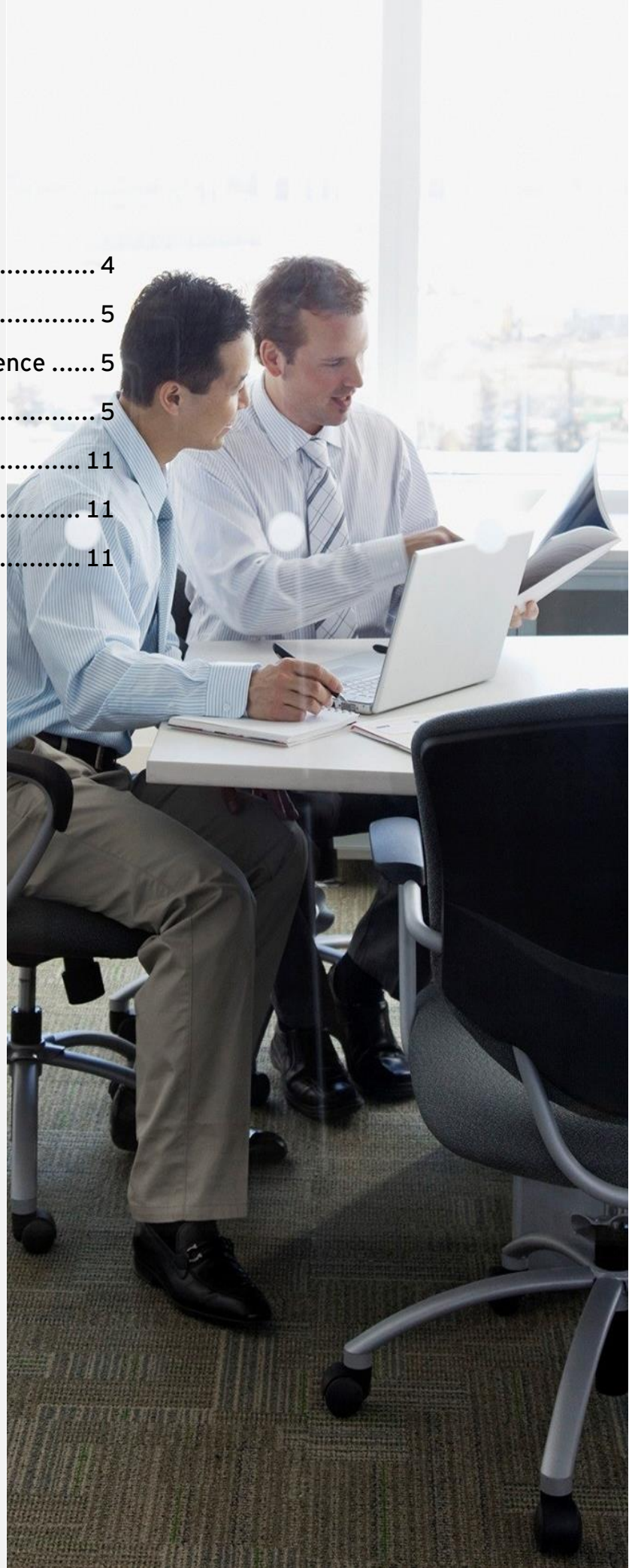
We appreciate the opportunity to provide our response to this RFI and welcome the chance to bring our thought leaders in to visit with AHCA leadership. Should you have questions about our response, please contact me at (850) 532-8825 or via email at ken.thomas@ey.com.

Sincerely,

Ken Thomas
Florida Government and Public Sector Leader

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Respondent information

A. *The Respondent's name; place of business address(s); Web Site address, if applicable; and contact information, including representative name and alternate, with telephone number(s) and e-mail address(s);*

Respondent Name: Ernst & Young U.S. LLP

Place of business address: 210 E. College Ave, Tallahassee, FL 32301

Web site address: www.ey.com

Contact information:

Ken Thomas
Ernst & Young LLP
Florida Government & Public Sector Leader
Tallahassee, FL
Ken.Thomas@ey.com
(850) 532-8825

Alternate contact information:

Dawn Woods
Ernst & Young LLP
State of Florida Advisory Account Leader
Tallahassee, FL
camilla.woods@ey.com
(404) 751-8861

Statement of interest

B. A statement of interest in or knowledge of the services outlined in this RFI, including any specific product, concept, technology, or approach that would meet the goals and requirements described in this RFI;

Ernst & Young LLP (EY) is excited at the opportunity to work with the State of Florida Agency for Health Care Administration ("AHCA") to better understand the opportunity and requirements for standing up a Canadian Prescription Drug Importation Program (the "Program"). Universal and equitable coverage for prescription drugs is a critical policy and program question for Florida - one that has received broad attention and resulted in differing approaches to address the challenges in drug coverage at both state and federal levels. The sustainability of the current state from a spend and cost perspective is of significant concern to all Floridians.

In this early planning and information gathering phase, we are pleased to offer AHCA leadership an opportunity to engage with experienced resources from our Health and Life Sciences Advisory group to explore best practices for addressing pharmaceutical import/export. Additionally, we can also offer experienced resources from our Supply Chain Advisory practice, which will give AHCA leadership clear insights into the best approach for operational design and execution of the program at large. Both of these specialty areas are cornerstone to EY's brand globally and bring mature, robust processes, methodologies and enabling technology with accelerators to support all phases from program design to implementation to operational oversight.

Multiple perspectives and potential challenges must be considered as Florida evaluates this initiative, which has regulatory, policy, and logistical implications for both sides of the border. Our approach to support AHCA draws on the expertise and reach of our global firm to provide comprehensive analysis and support in all three of these key program areas.

Respondent business and related experience

C. A description of the Respondent's business and its experience as it relates to the services outlined in this RFI. This description should include a narrative explaining past experiences related to pharmaceutical importation or exportation. The respondent shall indicate any international or wholesale distribution experience it has for services similar in nature to those described in this RFI.


About EY

EY is a global leader in assurance, tax, transaction and advisory services. Worldwide, EY's over 260,000 people are united by shared values and an unwavering commitment to quality. We make a difference by being committed to helping our people and clients build a better working world.

While EY is a global organization, its presence locally is just as impressive. Our US Government and Public Sector Practice brings significant experience at both the State and Federal Health and Human Services levels which, coupled with a very strong Canadian Health practice, brings AHCA depth across the entire ecosystem of which this program initiative is derived from.

The strengths of our experience include:

Why EY	Key Strengths we bring to AHCA
A firm with international access to payers who have implemented various types of public coverage schemes for prescription drugs	<ul style="list-style-type: none"> • We work in 140 countries and have consultants who have insight into the payer landscape for pharmaceuticals, and Medicare / Pharmacare programs in many of these countries • Our deep relationships with health care agencies and governments in each country affords us the qualitative perspective on models and implementation considerations that cannot be accessed through literature and reports alone
Direct experience working with countries across the globe as they assess and implement new payment models for pharmaceutical products	<ul style="list-style-type: none"> • We have worked directly on projects related to national pharmaceutical payment models, access and distribution as well as governance across different jurisdictions • Recent jurisdictional scan results from work in the US, Brazil, Australia, Nordica, Africa, UK, India and Singapore will be available for this project
Dedicated Healthcare and Life Sciences team in the US, Canada and across the globe who work every day with health payers, insurers, and drug manufacturers	<ul style="list-style-type: none"> • We have national and global practices focused exclusively on health care and life sciences • This results in deep knowledge of all aspects of the sector from payers to providers to private insurers and pharmaceutical companies • For example, in Canada we have supported the: <ul style="list-style-type: none"> ◦ Generic Drug Agreement and Pharmaceutical Task Force; ◦ Drug Purchasing and Negotiation (Health Shared Services BC - Lower Mainland Consolidation); and ◦ Rare Disease Risk Pooling Recommendations. • In the US, we have worked with insurers as they assessed the impact of the US proposed Affordable Care Act and are now active with a quality review in partnership with Johns Hopkins University and the Veterans Administration • Assessment of emerging markets in pharmaceuticals in Africa and South America and implications for healthcare
Independence and objectivity	<ul style="list-style-type: none"> • As we work with clients representing relevant stakeholder groups, including public payers, health care providers, patients, private payers, and employers, we have an interest in looking for the solution that maximizes the benefits for all citizens • Independence and objectivity is at the core of how we work with our clients, and allows us to provide balanced analyses and recommendations leveraging all views and perspectives

Why EY	Key Strengths we bring to AHCA
<p>Rigorous approaches to program design, driven by evidence and focused on outcomes</p>	<ul style="list-style-type: none"> • We will bring the industry's most advanced tools and accelerators to apply best practices in planning for this initiative by giving AHCA access to thought leadership reports, policy and analysis in addition to our own Healthcare and Life Sciences Thought Leadership Research and Reports <p>Some examples include:</p> <ul style="list-style-type: none"> • <i>State drug pricing laws: overview of state price transparency and other legislative trends (2018)</i> - Overview of recent trends and approaches by various state payers to contain the increase in drug plan costs • <i>Progressions 2014: Navigating the Payer Landscape</i> - Provides perspectives on enabling closer and more value-added collaborations between manufacturers and payers • <i>March 2015: Globalization and Outsourcing of R&D in the Pharmaceutical Industry</i> - Looks at the impact on patients' access to pharmaceuticals • <i>Launch Sequencing (2018) - An assessment of Canada's current and potential future attractiveness as a launch destination for innovative medicines</i> - A quantitative analysis of new product launches in Canada from 2011-2017, looking at launch delays and launch counts relative to other developed markets. <div data-bbox="732 978 1315 1150">  </div>

EY's purpose: Building a better working world

EY is committed to doing its part in building a better working world.

We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our clients and their communities.

EY Advisory Services

Worldwide, our Advisory practice is close to 34,500 professionals who help clients by using strategy to help drive their business performance, addressing the strategic and operational risks to help protect their businesses and embracing innovation and emerging technologies to extend the reach of their organizations.

EY Government and Public Sector (GPS) practice

Our Government and Public Sector (GPS) practice is a network of highly skilled professionals from our assurance, tax, transaction, and advisory practices dedicated to serving local government and public sector organizations. Through a collaborative approach, we combine

a wealth of consulting capabilities – strategy, customer, finance, IT, supply chain, people and

organizational change, program management and risk – with a comprehensive understanding of a client's most complex issues and opportunities. This practice allows our professionals to provide:

- ▶ Tailored services and approaches specifically for the government and public sector
- ▶ Relevant and timely insight on government public sector issues and pronouncements
- ▶ A strong bench of professionals to provide high-quality service
- ▶ The ability to better understand and manage government public sector risks
- ▶ Consistent industry training of our people

We have a strong history and experience in servicing GPS clients (including state & local agencies, municipalities, provincial and federal governments) within Florida, across the US and Canada, and Internationally.

Health Care and Life Sciences Focus

Changes in demographics, health care policy, and market access strategies are driving dramatic change in Health Care and Life Sciences both in the US and globally. Payers must rethink their strategies, collaboration models, and the concept of value in order to achieve sustainability in the face of the increasing price of drugs, driven by numerous factors, including manufacturer pricing strategies, as well as the rise in availability of new specialty drugs that can be life-changing for patients, but which also carry higher price tags.

It would be our pleasure to assemble a team for AHCA that has extensive knowledge and experience of both the US and Canadian pharmaceuticals environments from payer, provider, and manufacturer perspectives. We work with many Ministries and Departments of Health, Health Authorities, health agencies, hospitals, and shared service delivery organizations, in addition to our work with the pharmaceutical industry. This enables us to support our clients in policy, strategy development, cost management, performance improvement, as well as implementation of these approaches.

Our team would include leaders with experience from both sides of the border, providing us with a unique ability to help AHCA navigate the issues inherent in the program design and bridge the connections needed for results and true partnership.

In the US, we have the right resources who bring a keen understanding of the Medicaid landscape and overarching objectives, along with an understanding of the pharmaceutical industry, including likely responses to the program. In Canada, we have individuals who have worked extensively with Canadian and US life sciences clients on a variety of strategic engagements to help them define market access strategies and programs that address the need to balance patient access with drug plan sustainability. They also have experience in implementation of drug plans and negotiation of drug agreements with manufacturers and can provide perspectives from a negotiations standpoint.

As we have the opportunity to engage with AHCA, we will offer a team comprised of individuals from a variety of backgrounds including economic and financial analysis, program design, strategy and business model design, and stakeholder engagement. We believe that these qualities will be essential for any vendor working with AHCA to establish a Canadian Prescription Drug Importation Program.

Since we operate in a borderless manner, we draw on our extensive firm resources to bring leading practices, tools and lessons learned from strategic as well as process initiatives in other jurisdictions. For example, we are a thought leader in Life Sciences as evidenced through our regular publications such as our Progressions series. Through our senior experts and our strong network of relationships

(e.g., payers, providers, policy makers, Life Sciences executives and outside the industry), we help our clients ask better questions and provide regular, unique insight and ideas to help challenge their thinking. Publications such as Progressions provide regular insights on the industry and provide guidance to industry stakeholders on key issues, challenges and trends.

Estimate of Implementation Costs

D. An estimate of administrative and operational costs associated with implementing the program.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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- What regulations and/or policies need to be established or aligned with either Federal or

Estimate of Recurring Costs

E. An estimate of administrative and operational costs associated with sustaining the program.

Timeline

F. An estimated timeline for program implementation.

Innovative Ideas and Strategies

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G. A description of innovative ideas and strategies in providing the services described in this RFI. As a part of the response, include any potential implementation challenges that the respondent believes the Agency should consider during the Program design phase and potential solutions.

[REDACTED]

Program scope

[REDACTED]

Patient access

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Supply Chain

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Summary

In summary, EY is well equipped to address the program elements by asking the right questions. Asking better questions will certainly help AHCA imagine a pioneer vision for providing greater opportunities in Florida's pharmaceutical market. We can help you develop a roadmap that determines the best next steps to take to design and implement this dynamic and complex initiative which is incredibly important to the Agency, the Florida State Government Leadership at large, and the citizens of Florida who we all serve. We welcome the opportunity to have a further discussion.

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About EY

EY is a global leader in assurance, tax, transaction and advisory services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our people, for our clients and for our communities.

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