Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments

Public Meeting
June 7, 2022
9:30 – 10:50 AM

9:35 – 9:40 AM

WELCOME AND INTRODUCTION

Jay Tyler
Chief Financial Officer
Office of Finance, Budget, Acquisitions, and Planning

Agenda

Topic	Presenter	Time
Begin Meeting	**Monica Ellerbe** Director, Business Management Services Office of Finance, Budget, Acquisitions, and Planning	9:30 – 9:35 AM
Welcome and Introduction	**Jay Tyler** Chief Financial Officer Office of Finance, Budget, Acquisitions, and Planning	9:35 – 9:40 AM
Update on 5-Year Financial Plans	**Brandon Lee** Supervisory Operations Research Analyst, User Fees Support Staff, Office of Financial Management Office of Finance, Budget, Acquisitions, and Planning	9:40 – 10:00 AM
Resource Capacity Planning (RCP) Implementation Updates	**Andrew Kish** Director, Office of Program and Strategic Analysis Center for Drug Evaluation and Research **Josh Barton** Director, Resource Capacity Planning Staff, Office of Program and Strategic Analysis Center for Drug Evaluation and Research	10:00 – 10:40 AM
Wrap Up & Additional Information	**Monica Ellerbe** Director, Business Management Services Office of Finance, Budget, Acquisitions, and Planning	10:40 – 10:50 AM
	Total Time	**80 minutes**

9:40 – 10:00 AM

UPDATE ON 5-YEAR FINANCIAL PLANS

Brandon Lee
Supervisory Operations Research Analyst, User Fees Support Staff, Office of Financial Management
Office of Finance, Budget, Acquisitions, and Planning

Overview of the PDUFA Financial Plan

Budgetary Resources	FY 2018	FY 2019	FY 2020	FY 2021		FY 2022
	Actual	Actual	Actual	Estimate	Actual	Estimate
Target Revenue	**$911,346,000**	**$1,010,322,000**	**$1,074,714,000**	**$1,107,199,000**	**$1,107,199,000**	**$1,200,129,000**
Cash Collections	$908,077,723	$1,015,152,012	$1,020,229,037	$1,107,199,000	$1,152,538,861	$1,200,129,000
Recoveries	$13,149,599	$12,857,171	$28,773,047	$12,000,000	$7,945,861	$12,000,000
Carryover Available for Use, Beginning of Year	$350,108,200	$209,223,938	$220,088,812	$193,603,985	$193,603,985	$244,902,650
Total Budgetary Resources	**$1,271,335,522**	**$1,237,233,121**	**$1,269,090,895**	**$1,312,802,985**	**$1,354,088,707**	**$1,457,031,650**

User Fee Obligations	FY 2018	FY 2019	FY 2020	FY 2021		FY 2022
	Actual	Actual	Actual	Estimate	Actual	Estimate
Payroll & Operating						
CBER	$129,543,398	$132,847,629	$136,614,045	$149,475,247	$150,521,826	$163,802,977
CDER	$688,935,477	$632,811,258	$685,618,671	$698,930,717	$704,118,513	$753,055,633
CDRH	$786,091	$1,501,379	$3,360,240	$4,122,893	$2,344,727	$4,239,557
ORA	$7,733,467	$7,443,695	$7,553,941	$8,753,009	$7,143,725	$9,312,383
HQ	$54,211,488	$55,910,342	$51,768,233	$59,746,750	$58,497,784	$55,401,955
Total Rent	$49,964,883	$52,437,964	$53,231,596	$66,590,414	$59,341,292	$63,162,874
Total Shared Services	$130,936,781	$134,192,042	$137,340,185	$135,434,813	$127,218,191	$124,845,109
Total Obligations	**$1,062,111,583**	**$1,017,144,309**	**$1,075,486,910**	**$1,123,053,843**	**$1,109,186,057**	**$1,173,820,489**

Carryover	FY 2018	FY 2019	FY 2020	FY 2021		FY 2022
	Actual	Actual	Actual	Estimate	Actual	Estimate
Total Carryover, End of Year	$209,223,938	$220,088,812	$193,603,985	$189,749,142	$244,902,650	$283,211,161
Unappropriated Amounts	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)
Future Year Refunds Allowance, Set Aside	$0	$0	($20,000,000)	($20,000,000)	($20,000,000)	($20,000,000)
Carryover Available for Use, End of Year	**$130,372,943**	**$141,237,817**	**$94,752,990**	**$90,898,147**	**$146,051,655**	**$184,360,166**

Target Revenue has been rounded to the nearest thousand dollars
All other numbers have been rounded to the nearest dollar

Collection Shortfall

- Cohort year 2021 collections exceeded the revenue target by over 4%.

Carryover Balance

- Operations in FY 2021 resulted in a net increase of the carryover balance due to an increase in application fee and program fee collections.
- The carryover net of unavailable and set-aside is now approximately seven weeks of available operating reserve levels.

Overview of the BsUFA Financial Plan

Budgetary Resources	FY 2018	FY 2019	FY 2020	FY 2021		FY 2022
	Actual	Actual	Actual	Estimate	Actual	Estimate
Target Revenue	**$40,214,000**	**$38,847,000**	**$41,923,000**	**$42,493,000**	**$42,493,000**	**$40,040,000**
Cash Collections	$29,238,601	$34,685,713	$37,971,967	$42,493,000	$42,705,959	$40,040,000
Recoveries	$1,074,997	$456,236	$535,834	$600,000	$420,828	$600,000
Carryover Available for Use, Beginning of Year	$48,723,308	$38,757,343	$31,840,903	$36,475,695	$36,475,695	$45,956,772
Total Budgetary Resources	**$79,036,907**	**$73,899,291**	**$70,348,704**	**$79,568,695**	**$79,602,481**	**$86,596,772**

User Fee Obligations	FY 2018	FY 2019	FY 2020	FY 2021		FY 2022
	Actual	Actual	Actual	Estimate	Actual	Estimate
Payroll & Operating						
CBER	$-	$-	$46,149	$304,080	$20,173	$310,405
CDER	$31,113,433	$33,004,440	$25,932,156	$32,781,241	$26,244,410	$36,143,181
ORA	$1,128,256	$676,738	$1,092,113	$1,460,366	$1,094,666	$1,500,956
HQ	$2,293,521	$1,529,197	$1,297,005	$1,627,682	$1,303,454	$1,310,362
Total Rent	$1,104,785	$1,382,811	$732,615	$1,551,504	$866,814	$1,567,019
Total Shared Services	$4,639,568	$5,465,202	$4,772,972	$4,474,100	$4,116,192	$2,947,378
Total Obligations	**$40,279,564**	**$42,058,388**	**$33,873,010**	**$42,198,973**	**$33,645,709**	**$43,779,302**

Carryover	FY 2018	FY 2019	FY 2020	FY 2021		FY 2022
	Actual	Actual	Actual	Estimate	Actual	Estimate
Total Carryover, End of Year	$38,757,343	$31,840,903	$36,475,695	$37,369,722	$45,956,772	$42,817,470
Future Year Refunds Allowance, Set Aside	($500,000)	($500,000)	($1,000,000)	($1,000,000)	($1,000,000)	($1,000,000)
Carryover Available for Use, End of Year	**$38,257,343**	**$31,340,903**	**$35,475,695**	**$36,369,722**	**$44,956,772**	**$41,817,470**

Target Revenue has been rounded to the nearest thousand dollars
All other numbers have been rounded to the nearest dollar

Collection Shortfall

- Cohort year 2021 collections were short of the revenue target by less than 1%.

Carryover Balance

- Operations in FY 2021 resulted in a net increase of the carryover balance, exceeding the 21-week operating reserve commitment level.
- FDA plans to use the carryover amounts in excess of the 21-week amount to support funding of certain program investments related to negotiated BsUFA III initiatives.
- The primary driver of the increase is the impact of COVID-19-related efforts, as well as fewer-than-expected submissions, which caused a decrease in payroll spending.

Overview of the GDUFA Financial Plan

Budgetary Resources	FY 2018	FY 2019	FY 2020	FY 2021		FY 2022
	Actual	Actual	Actual	Estimate	Actual	Estimate
Target Revenue	**$493,600,000**	**$501,721,000**	**$513,223,000**	**$520,209,000**	**$520,209,000**	**$539,656,000**
Cash Collections	$493,655,974	$496,503,494	$483,285,782	$520,209,000	$500,205,882	$539,656,000
Recoveries	$4,920,184	$8,544,957	$9,968,653	$7,000,000	$6,535,880	$7,000,000
Carryover Available for Use, Beginning of Year	$142,412,048	$163,715,667	$204,171,168	$156,731,582	$156,731,582	$127,223,404
Total Budgetary Resources	**$640,988,205**	**$668,764,117**	**$697,425,603**	**$683,940,582**	**$663,473,344**	**$673,879,404**

User Fee Obligations	FY 2018	FY 2019	FY 2020	FY 2021		FY 2022
	Actual	Actual	Actual	Estimate	Actual	Estimate
Payroll & Operating						
CBER	$49,462	$23,658	$131,615	$1,018,541	$118,344	$1,040,390
CDER	$323,591,582	$316,437,772	$378,276,891	$385,402,867	$384,542,262	$399,022,266
ORA	$46,518,651	$40,694,363	$48,355,675	$49,604,248	$41,354,289	$51,129,752
HQ	$27,801,624	$27,565,531	$35,022,863	$37,774,571	$29,770,574	$35,060,496
Total Rent	$22,019,962	$24,962,969	$19,802,082	$26,313,583	$23,037,004	$26,576,719
Total Shared Services	$57,291,257	$54,908,657	$59,104,896	$60,980,714	$57,427,467	$64,738,821
Total Obligations	**$477,272,539**	**$464,592,949**	**$540,694,021**	**$561,094,525**	**$536,249,940**	**$577,568,444**

Carryover	FY 2018	FY 2019	FY 2020	FY 2021		FY 2022
	Actual	Actual	Actual	Estimate	Actual	Estimate
Total Carryover, End of Year	$163,715,667	$204,171,168	$156,731,582	$122,846,058	$127,223,404	$96,310,960
Future Year Refunds Allowance, Set Aside	($5,000,000)	($5,000,000)	($4,000,000)	($4,000,000)	($4,000,000)	($4,000,000)
Carryover Available for Use, End of Year	**$158,715,667**	**$199,171,168**	**$152,731,582**	**$118,846,058**	**$123,223,404**	**$92,310,960**

Target Revenue has been rounded to the nearest thousand dollars
All other numbers have been rounded to the nearest dollar

Collection Shortfall

- Cohort year 2021 collections were short of the revenue target by 4%.

Carryover Balance

- Operations in FY 2021 resulted in a net decrease of the carryover balance. The decrease was primarily driven by actual collections being less than estimated in FY 2021.

10:00 – 10:40 AM

RESOURCE CAPACITY PLANNING IMPLEMENTATION UPDATES

Andrew Kish
Director, Office of Program and Strategic Analysis
Center for Drug Evaluation and Research

Josh Barton
Director, Resource Capacity Planning Staff, Office of Program and Strategic Analysis
Center for Drug Evaluation and Research

RESOURCE CAPACITY PLANNING PROGRESS REVIEW

PDUFA VI, BsUFA II, and GDUFA II included a set of Resource Capacity Planning commitments

FDA is committed to enhancing management of PDUFA resources in PDUFA VI. FDA will conduct activities to develop a resource capacity planning function and modernized time reporting approach in PDUFA VI.

1. Implementation Plan

1. FDA will publish a PDUFA program resource capacity planning and modernized time reporting implementation plan no later than the 2nd quarter of FY 2018. FDA will continue to utilize information and recommendations from a third-party assessment of resource capacity planning, financial analytics, and modernized time reporting for PDUFA as part of the implementation plan.

2. Staff RCP Team

2. FDA will staff a resource capacity planning team that will implement and manage a capacity planning system across the PDUFA program in PDUFA VI.

3. CPA Methodology

3. FDA will obtain through a contract with an independent accounting or consulting firm an evaluation of options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the human drug review program. The report will be published no later than end of FY 2020 for public comment. Upon review of the report and comments, FDA will implement robust methodologies for assessing resource needs of the program. This will include the adoption of a new resource capacity adjustment methodology, in place of the current PDUFA workload adjuster, that accounts for sustained increases in PDUFA workload.

4. Financial Reporting

4. FDA recognizes that revenue generated by the workload adjuster and the resource capacity adjustment will be allocated to and used by organizational review components engaged in direct review work to enhance resources and expand staff capacity and capability. FDA will document in the annual financial report how the workload adjuster and resource capacity adjustment fee revenues are being utilized.

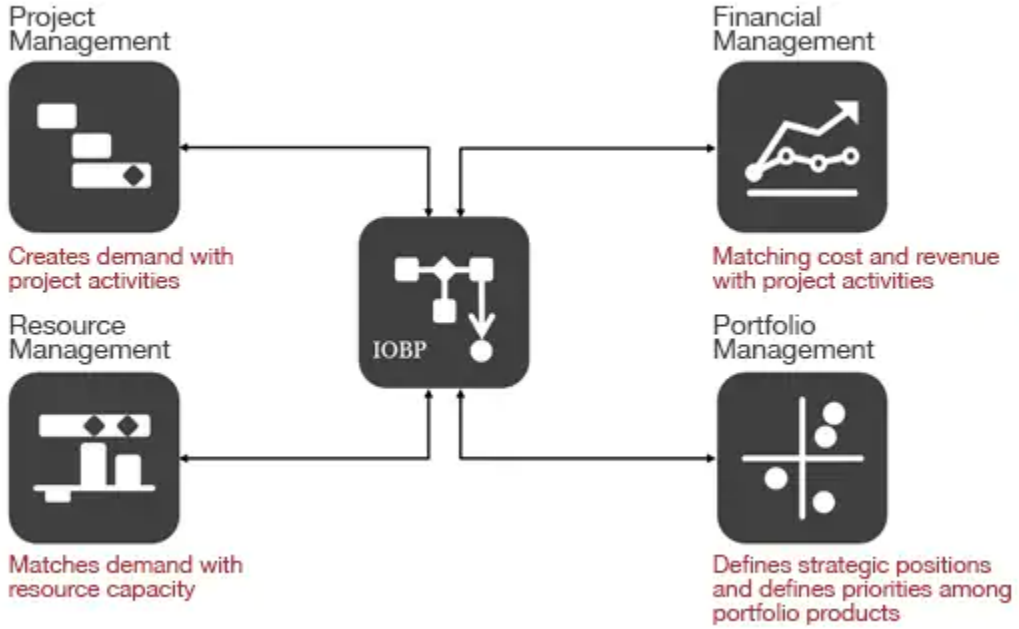
RCP and MTR Implementation Plan

Commitment:

- FDA will publish a PDUFA program resource capacity planning and modernized time reporting implementation plan no later than the 2nd quarter of FY 2018. FDA will continue to utilize information and recommendations from a third-party assessment of resource capacity planning, financial analytics, and modernized time reporting for PDUFA as part of the implementation plan.

How we delivered on this:

- Through a competitive process, FDA hired PricewaterhouseCoopers (PwC) as the third-party to assess and advise on its approach to implementing Resource Capacity Planning
- PwC's private-sector Pharmaceutical & Life Sciences R&D Advisory Services helped to fit their **Integrated Operations and Business Planning (IOBP) framework** to fit the needs of these UFA programs to enable RCP
- FDA worked to align on an approach to meet the commitments across its organizational components by adapting the IOBP to its operating paradigm
- FDA outlined its approach in its **Resource Capacity Planning and Modernized Time Reporting Implementation Plan** published in March 2018



Staff a Resource Capacity Planning Team

Commitment:

- FDA will staff a resource capacity planning team that will implement and manage a capacity planning system across the PDUFA program in PDUFA VI.

How we delivered on this:

- The Resource Capacity Planning Staff established in CDER to serve as the lead on RCP activities in collaboration with CBER.
- HQ team established to support implementation, operations and maintenance of the Insight Time Reporting application.

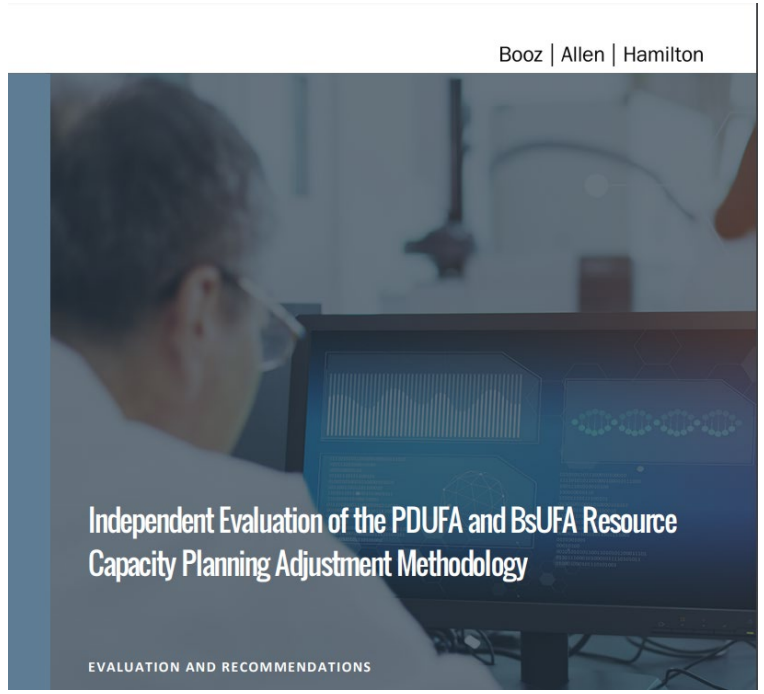
CPA Methodology

Commitment:

- FDA will obtain through a contract with an independent accounting or consulting firm an evaluation of options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the human drug review program. The report will be published no later than end of FY 2020 for public comment. Upon review of the report and comments, FDA will implement robust methodologies for assessing resource needs of the program. This will include the adoption of a new resource capacity adjustment methodology, in place of the current PDUFA workload adjuster, that accounts for sustained increases in PDUFA workload.

How we delivered on this:

- FDA commissioned with Booz Allen Hamilton to conduct two evaluations:
  - PDUFA/BsUFA methodology
  - GDUFA methodology
- Both published in FY 2020. Findings endorsed the methodology while providing considerations for future enhancements.



Allocation and Reporting of CPA Funds

Commitment:

- FDA recognizes that revenue generated by the workload adjuster and the resource capacity adjustment will be allocated to and used by organizational review components engaged in direct review work to enhance resources and expand staff capacity and capability. FDA will document in the annual financial report how the workload adjuster and resource capacity adjustment fee revenues are being utilized.

How we delivered on this:

- Process established to ensure distribution of revenue generated by the CPA are allocated to review components in CDER & CBER.
- Documentation added to annual financial reports on the distribution of these resources.

Next Steps

- Assuming reauthorization of the relevant UFA programs as negotiated, FDA will plan to:
  - Continue to deliver on the RCP and related commitments
  - Continuously improve existing RCP capabilities
  - Articulate an updated RCP plan for the next authorization cycle
  - Implement the CPA methodology for GDUFA

CAPACITY PLANNING ADJUSTMENT DEEP DIVE

Evolution of the Capacity Planning Adjustment

- PDUFA established in FY 1993 to provide predictable, stable revenue to enhance staffing and infrastructure for the review program
- The annual fee revenue amount did not change based on industry-submitted workload
  - When industry submissions increased, FDA had more review work it had to complete under the same performance timelines, with flat funding levels
  - Growth in program workload during PDUFA II became unsustainable
- Industry and FDA agreed to a mechanism to address this problem in PDUFA III: the PDUFA Workload Adjuster
  - The PDUFA Workload Adjuster adjusted the annual revenue amount based on industry submissions
- Modifications and third-party studies followed in PDUFA IV and PDUFA V
  - A PDUFA V study found that the Workload Adjuster was not optimal, but the best feasible model available to FDA at the time
- In light of these findings, in PDUFA VI, industry and FDA agreed on a set of commitments to establish a resource capacity planning capability and to modernize its time reporting approach
  - Intent was, in part, for these capabilities to provide a foundation for a more optimal revenue adjustment based on changes in PDUFA workload
  - Mechanism was renamed as the ‘Capacity Planning Adjustment’
  - Statute provided an interim Capacity Planning Adjustment in the first years as well as a process to establish a new methodology and apply it for BsUFA as well

Evolution of the Capacity Planning Adjustment

- Goal of the CPA remains the same as the original Workload Adjuster: to ensure UFA program can maintain an appropriate level of funding for staff when workload is increasing

- The CPA provides a mechanism to adjust resource levels for year to year for industry-driven workload.
  - This mitigates the risk of over or under-estimating workload levels 7 years into the future during the reauthorization negotiation process.
  - Guessing at workload levels 7 years in the future will not be accurate – result likely to be either an under or over-resource user fee program.

- Without a CPA, sustained increases in industry submissions would result in a significance risk to performance of UFA timelines

Capacity Planning Adjustment Fundamentals

The Capacity Planning Adjustment (CPA) is:

- A modernized methodology and a renaming of the legacy PDUFA Workload Adjuster
- One output of the Resource Capacity Planning capability
- Used to adjust the annual fee and revenue amounts as needed for expected workload
- Run once annually as part of the annual fee and revenue process
- Scoped to account for changes in direct review workload submitted by industry
- Structured to forecast workload changes specific to each Center
- Driven by validated submission forecast models and actual time reporting data
- Inclusive of a process of internal checks to ensure that any adjustment to fee amounts is needed and can be realistically utilized to support needed staffing for forecasted direct review workload

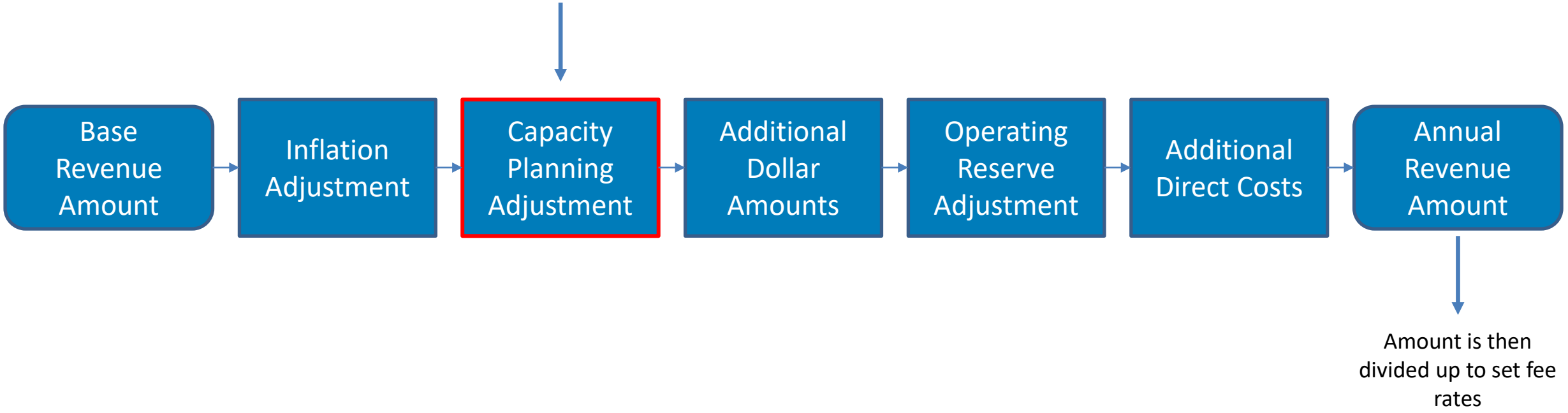
Key Terms

- Forecast – a practice of predicting future phenomenon based on the results of previous data

- Full-time equivalent (FTE) – refers to the number of hours expected to be worked by the equivalent of one full-time employee. Hours worked includes all leave taken.
  - 1 FTE = 2,080 annual hours (40 hours per week * 52 weeks per year)
  - 1 FTE does not equate to one distinct person or position. It is only a measure of hours

The CPA is one mechanism in the setting of the annual fee revenue amount

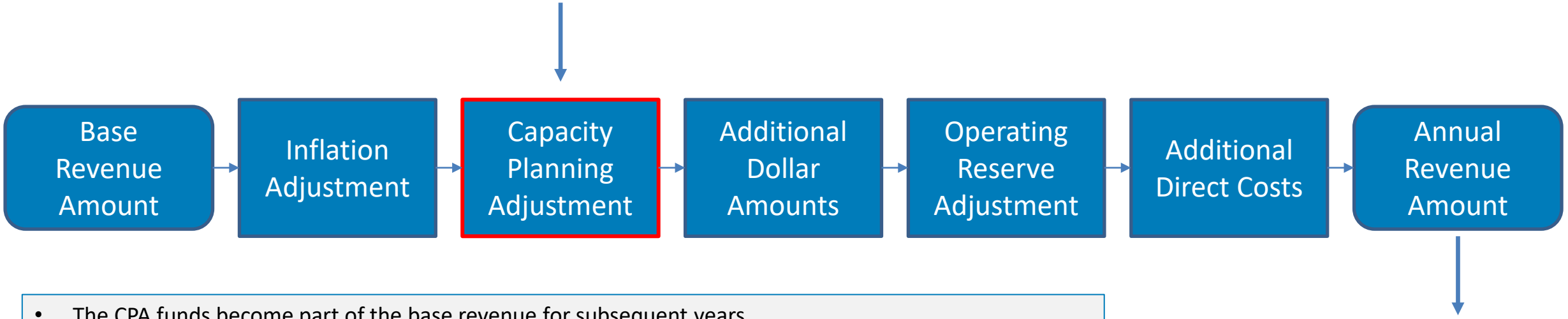
Current PDUFA revenue setting process*



* The BsUFA CPA plays a similar role in BsUFA fee-setting, though the BsUFA fee-setting process varies in other aspects from PDUFA

The CPA is one mechanism in the setting of the annual fee revenue amount

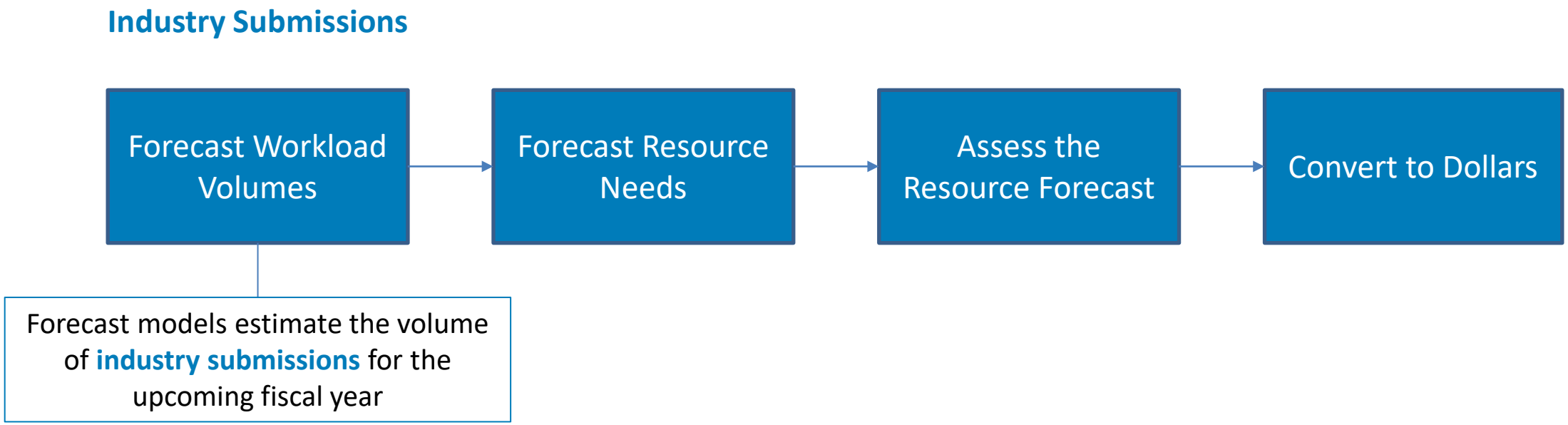
Current PDUFA revenue setting process*



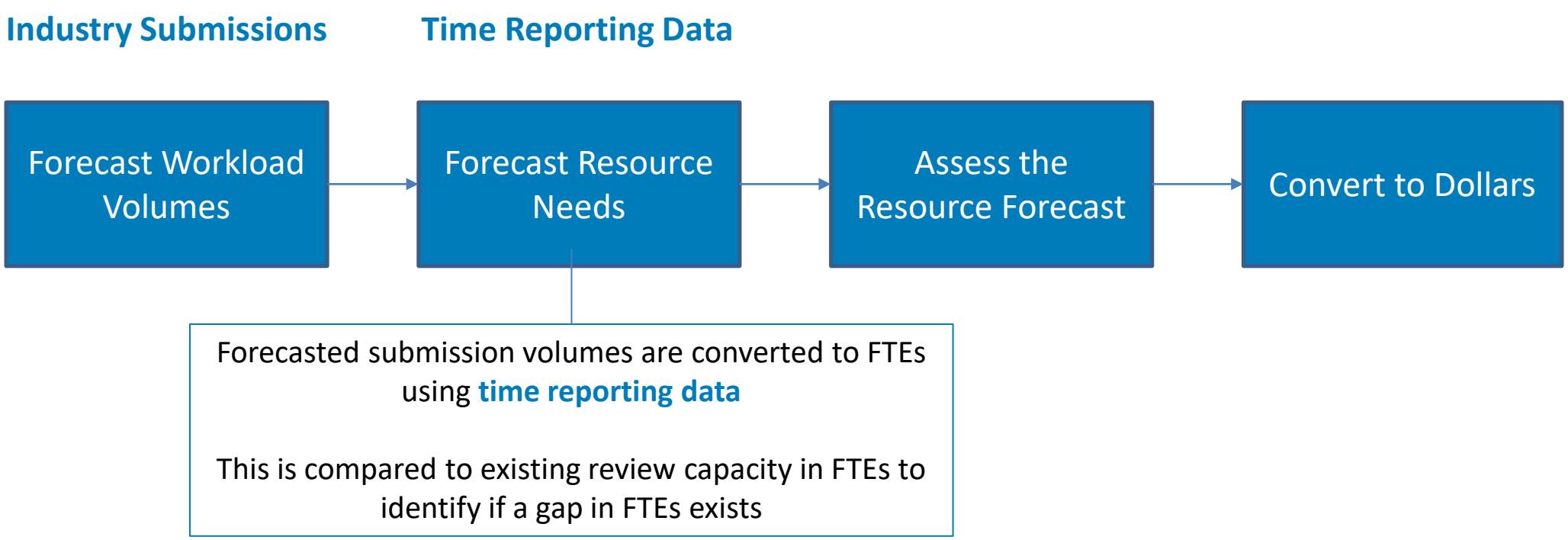
- The CPA funds become part of the base revenue for subsequent years.
  - This is necessary to **ensure predictable funding is available to support new staffing**
- This was a key part of the **negotiated change for PDUFA VI**
  - Prior to PDUFA VI, the Workload Adjuster funds were not guaranteed to be sustained in future years.
  - This meant FDA had to be very conservative in the use of the Workload Adjuster funds as it could not count on the funding to sustain new staffing in future years.

* The BsUFA CPA plays a similar role in BsUFA fee-setting, though the BsUFA fee-setting process varies in other aspects from PDUFA

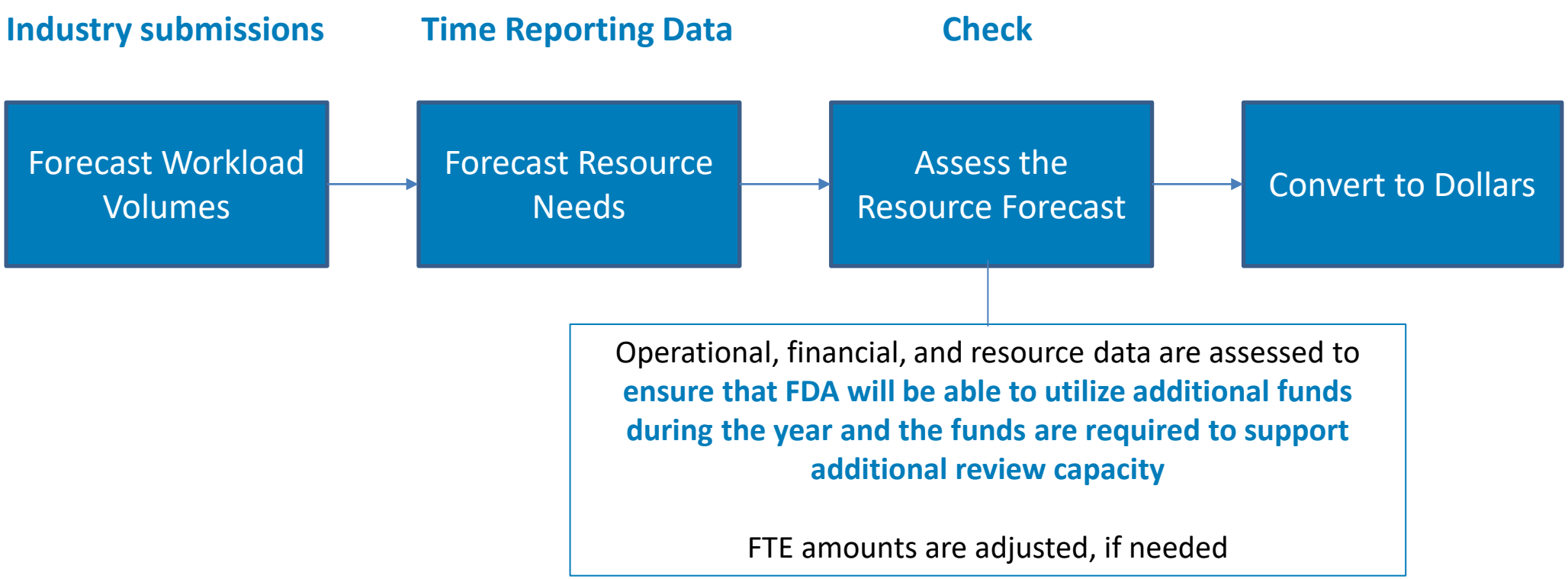
Overview of the CPA Process



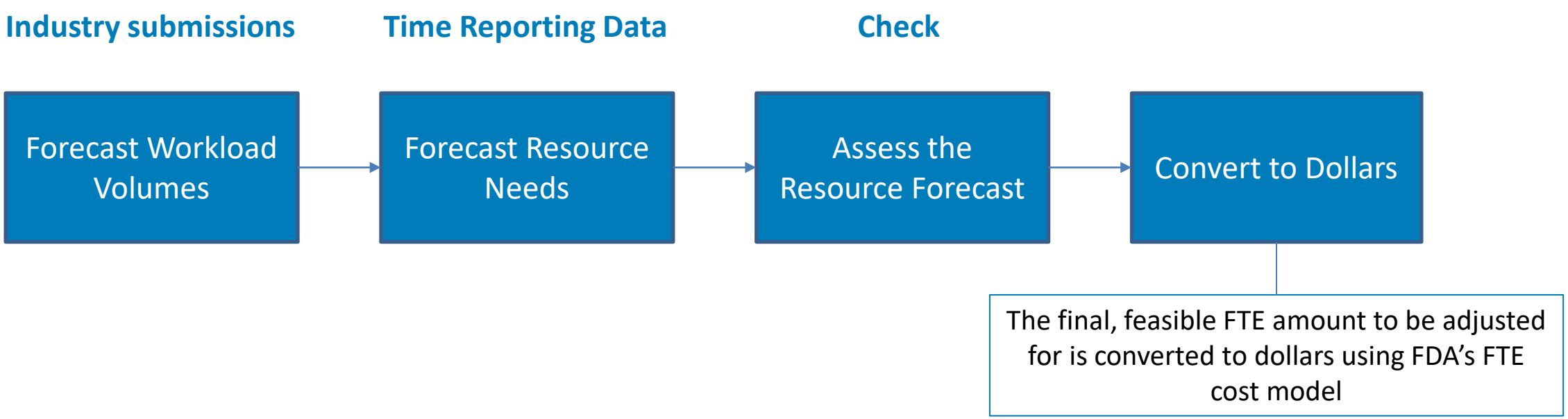
Overview of the CPA Process



Overview of the CPA Process



Overview of the CPA Process



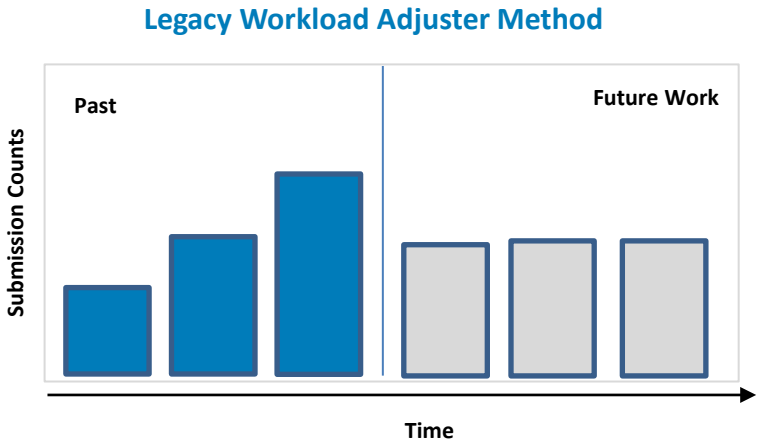
Why does the CPA Forecast Workload?

- The number of review staff needed are driven by the number of submissions received by the Agency
- FDA does not control the submission volume, but must review submissions within established timeframes regardless of the volume
- It takes time to hire and train review staff
- Thus, it is important to plan ahead to future expected workload levels to try to maintain adequate staffing levels

How does the CPA Forecast Workload?

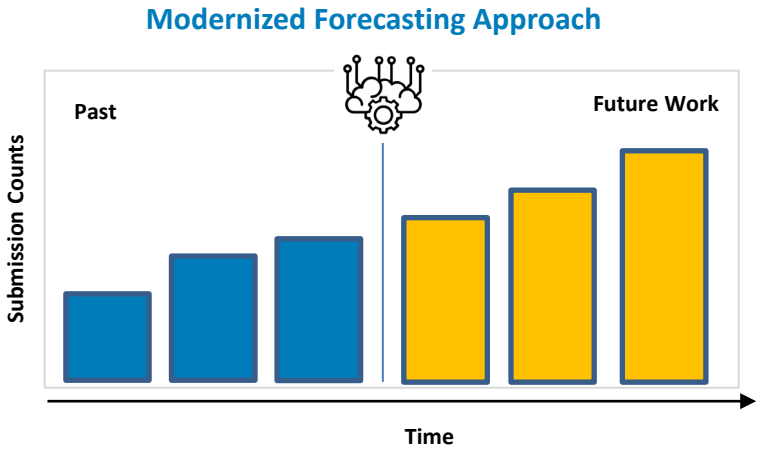
The legacy approach

- The Workload Adjuster used retrospective averages to account for changes in the volume of **industry submissions**
- This creates a potential structural gap in staff available to meet demand if the future is not the same…

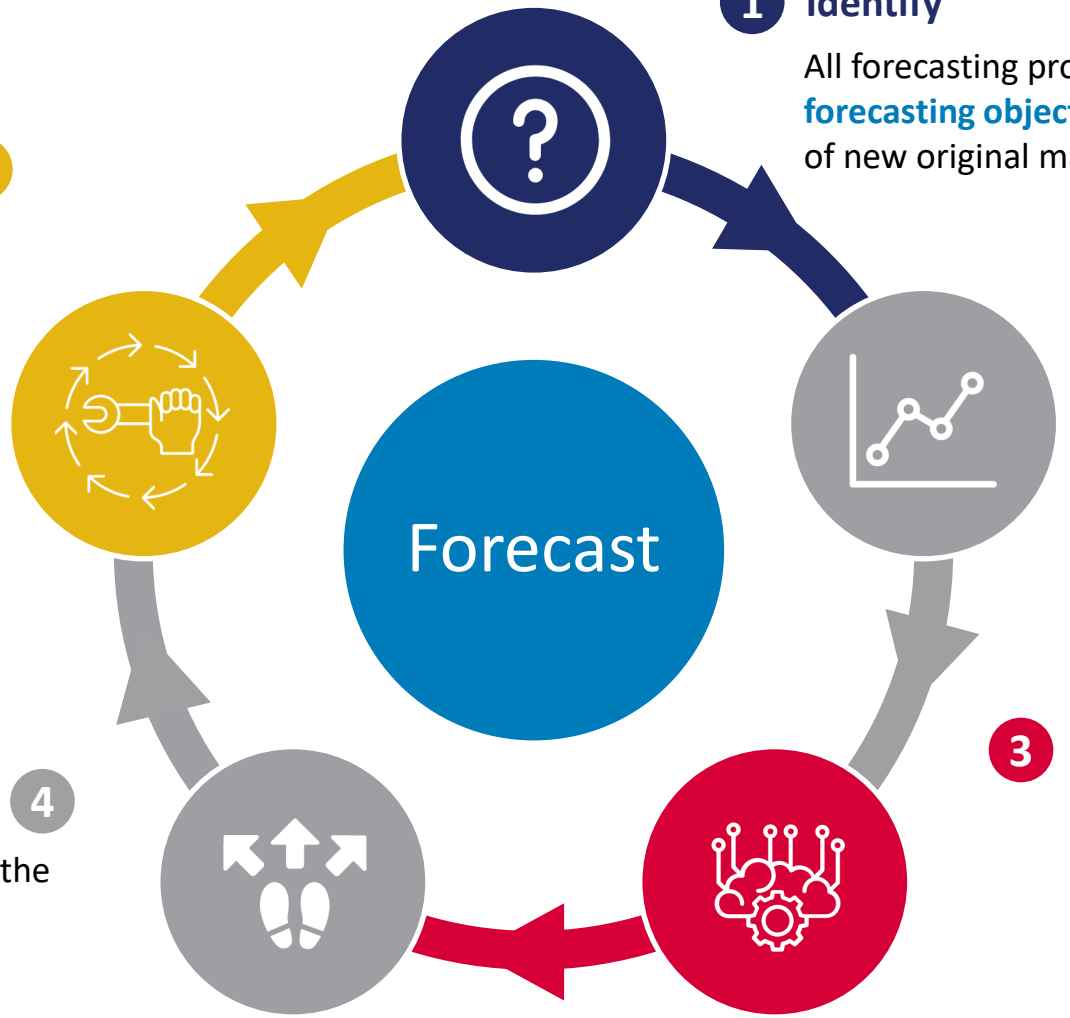


Looking forward to inform growth

- The CPA utilizes historical data in machine learning and other statistical models to predict volume of **industry submissions**
- By leveraging these data science techniques, we are well positioned to plan to likely workload levels



How does the CPA Forecast Workload?



1 Identify

All forecasting projects start with **identifying the forecasting objective:** e.g. identifying the likely volume of new original marketing applications

2 Understand

We analyze and **understand the underlying trends and drivers of a forecasted submission** (e.g. INDs to new NDA/BLA originals)

3 Model

We test **multiple machine learning methods** or include additional drivers in our model to best predict the future

Select 4

We select the model that performs the **best over time utilizing cross-validation** to **reduce bias** and avoid forecasting from a peak or a valley

Improve 5

We look at the problem each refresh and ask ourselves:

- Do our assumptions still hold true?
- **What can we improve** each refresh to **produce the most robust model?**

Industry submissions currently included:

6 PDUFA model sets

- NDA/BLA Originals *
- Active Commercial INDs *
- Efficacy Supplements *
- Manufacturing Supplements *
- Labeling Supplements
- Industry Meetings (Types A-C) **

** Included in Workload Adjuster since 2003*
*** Added by statute to Interim CPA in 2018*

6 BsUFA model sets

- Biosimilar BLA Originals
- BPD Programs
- Supplements with Clinical Data
- Manufacturing Supplements
- Labeling Supplements
- Industry Meetings (Types 1-4 & BIA)

Assuming reauthorization as negotiated, the CPAs will be updated to reflect new requirements, including a CPA for GDUFA

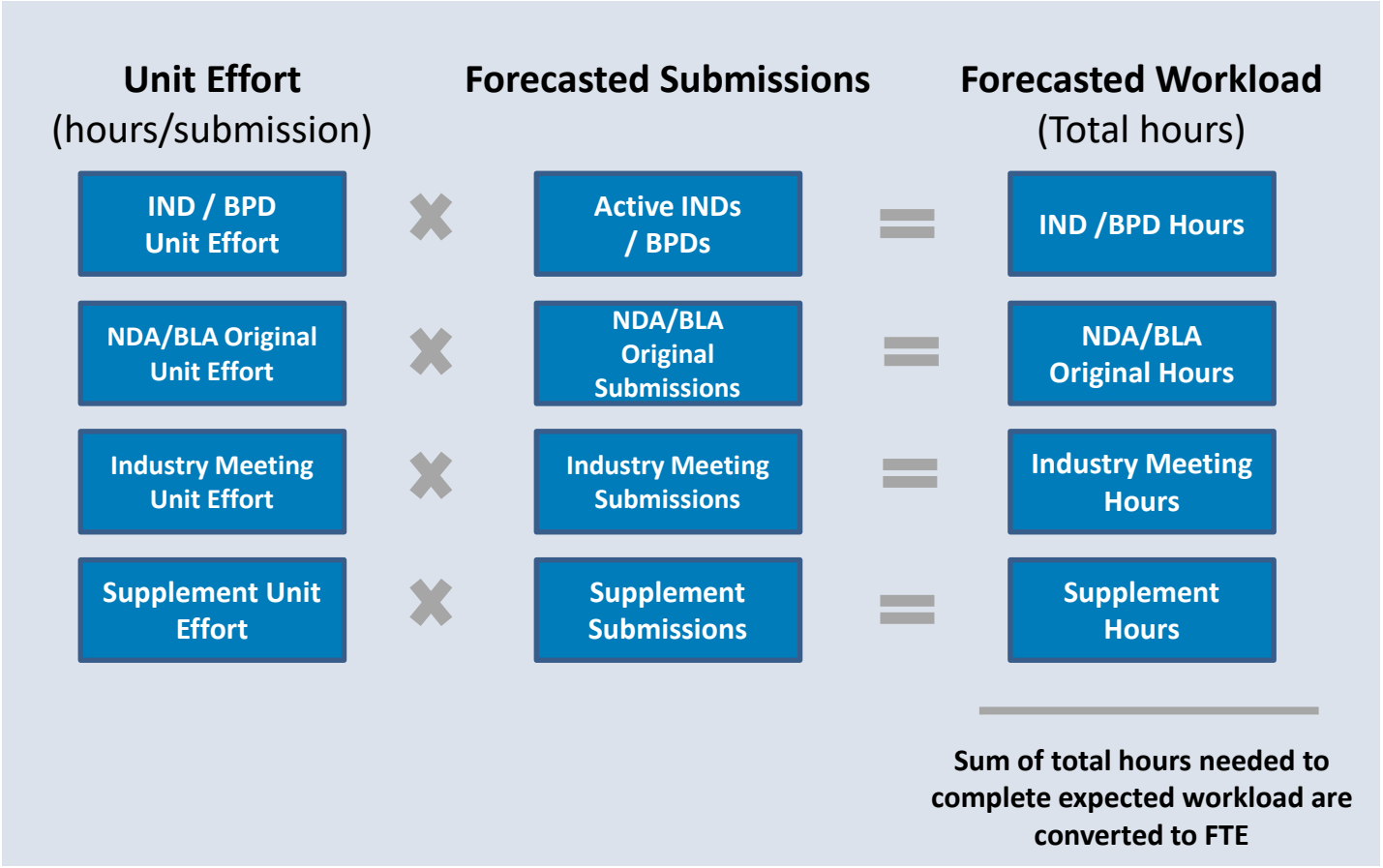
The CPA quantifies estimated time needed per submission with time reporting and historical submission data

- Modernized time reporting informs how much work is required to perform direct review activities, like the review of an original NDA
- Historical time reporting data and historical submissions are combined to form a unit effort, or the average time invested to complete the review of one submission
- This approach assumes that the historical investment of time is the appropriate investment of time

Illustrative Example: Using time reporting and submission data to establish an average number of hours of effort required per submission. This is known as 'unit effort.'

Forecasted submissions and unit effort are combined to form the total expected workload in FTE

Illustrative Example: Unit effort and forecasted submissions are combined and summed to form the total expected workload.



- Total hours needed to complete expected workload are converted to FTE and compared to current capacity
- An allocation of time is included to account for administrative tasks, training & leave
- If forecasted FTE needed exceed current capacity, then the difference would be assessed to ensure that FDA will be able to utilize additional funds during the year and the funds are required to support additional review capacity

Structured decision process to review CPA outputs

Referred to as the 'managerial adjustment,' this step assesses operational, financial, and resourcing data to ensure that any fee adjustment from the CPA can **be utilized to support the direct review workload during the fiscal year and that the funds are required to support additional review capacity**.

It includes factors such as:

- How the forecasts compare to prior year actuals – to assess forecast performance
- Whether forecasted changes are sustained – to prevent forecasting to a workload peak or valley
- Hiring and attrition considerations – to ensure that it is reasonably realistic to add the needed FTEs
- Financial considerations – to ensure that the funding is needed to fund the additional payroll

The factors considered are refined each year as more data become available.

The final output in FTEs are then converted to dollars using the FDA's FTE cost model.

Comparison of Workload Adjuster to CPA

Feature	Workload Adjuster	Capacity Planning Adjustment
Inputs	IND, NDA/BLA, Efficacy & CMC supplements	Same plus Labeling Supplements & Formal Industry Meetings
Submission estimation method	Lagging indicators	Leading indicators
Effort estimation method	Used convoluted and lagging standard cost methodology to weight submission volume percent changes	Actual time reporting data
Internal Check	None – reasonableness of adjustment not assessed	Introduced managerial adjustment as internal check on reasonableness of adjustment
Outputs	A percentage applied to the total annual revenue amount of the program	A measurement of needed FTE converted into dollar amounts by standard cost model
Sustainment of adjustment funds	None – the adjustment funds were not guaranteed in future years meaning no guarantee that payroll could be sustained	Negotiated incorporation of the adjustment funds into the base revenue to ensure new payroll can be sustained

CPA Next Steps

- Continuously refine and improve with additional data
- Implement new requirements (assuming reauthorization) including GDUFA CPA

RECAP OF RESOURCE CAPACITY PLANNING

What is Resource Capacity Planning?

- **Q: Why does the PDUFA program have a capacity planning adjustment**?

The capacity planning adjustment is a mechanism to adjust the annual target revenue to account for sustained increases in workload in order to ensure that the FDA is properly resourced to continue meeting its PDUFA performance commitments. Without the adjustment, FDA would be unable to keep up with increases in Industry driven workload in the program.

- **Q: Is the capacity planning adjustment a new concept?**

No, the precursor to the capacity planning adjustment was the PDUFA workload adjuster first adopted in PDUFA III. The capacity planning adjustment modernized the old workload adjuster methodology with advanced analytics and modernized time reporting.

- **Q: Is resource capacity planning intended to limit or greatly expand the growth in the PDUFA program?**

No, the resource capacity planning function is a data driven approach to accurately assess changes in the resource and capacity needs of the PDUFA program. Those changes are primarily driven by Industry activity.

What is Resource Capacity Planning?

- **Q: What are the main drivers of the capacity planning adjustment?**

There are two inputs into the capacity planning adjustment:

  - **Industry activity:** The volume of Industry submissions and formal meetings in the program (e.g., formal meetings scheduled and written response only, NDA/BLA submissions, commercial INDs with activity, supplements).
  - **Modernized time reporting:** FDA time reporting data that reflects how much effort it takes to complete that work.

- **Q: Can FDA increase the capacity adjustment to whatever it wants?**

No, FDA follows the analytical output from the capacity planning methodology and the managerial adjustment structured decision process to ensure reasonable and realistic adjustments. In fact, FDA has decreased the adjustment from the forecasted resource need via the managerial adjustment step the past two fiscal years.

- **Q: Does FDA have a way to do a reality check on the feasibility of acquiring new resources as part of the capacity planning adjustment?**

Yes, FDA included a managerial adjustment in the new CPA methodology as an internal control. This step assesses operational, financial, and resourcing data to ensure that any fee adjustment from the CPA can be utilized to support the direct review workload during the fiscal year. This includes a realistic assessment of hiring and attrition and looking for efficiencies to optimize the program.

10:40 – 10:50 AM

WRAP UP AND ADDITIONAL INFORMATION

Monica Ellerbe
Director, Business Management Services
Office of Finance, Budget, Acquisitions, and Planning

Wrap Up and Additional Information

To submit a public comment following this meeting, please follow these steps:

1. Go to Regulations.gov
2. Use Docket No. FDA-2019-N-1875 to locate this meeting
3. Submit your comment

You will have until **July 7, 2022, at 11:59 PM** Eastern Time to submit a comment.

To access the materials from this meeting, please visit the FDA.gov webpage listed below:

- 2022 Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments - 06/07/2022 | FDA